A DISSERTATION ON

# "A PROSPECTIVE INTERVENTIONAL STUDY BETWEEN CHEMICAL SPHINCTEROTOMY USING 2%TOPICAL DILTIAZEM AND SURGICAL INTERNAL SPHINCTEROTOMY IN THE MANAGEMENT OF CHRONIC FISSURE IN ANO"

Dissertation submitted to

**THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERISTY**

**CHENNAI**

with partial fulfilment of the regulations

for the Award of the degree

**M.S. (General Surgery)**

Branch – I


**INSTITUTE OF GENERAL SURGERY**,

**ESIC MEDICAL COLLEGE & PGIMSR, CHENNAI.**

**APRIL-2016**

**A Prospective Interventional Study between Chemical Sphincterotomy using 2%Topical Diltiazem And Surgical Internal Sphincterotomy in the management of Chronic Fissure in Ano**

**[Balasubramanian.A, Uday Kumbhar, Anbazhakan.]**

## ABSTRACT

Fissure in ano is the most common painful condition of perianal region, characterized by longitudinal ulcers affecting the distal part of the anal canal. It's so common that it affects 1 in 10 people and causes very disabling symptoms such as severe cutting type perianal pain & bleeding per rectum making the diseased to suffer intense mental &physical agony in spite of rest and analgesics. Also the chronic fissures behave more differently in that way they are more persistent and relapsing than the Acute fissures which are self-healing.

Much has been already discussed in the literature regarding the aetiology of Fissures though the Persistent Hypertonia of the anal sphincters is claimed to be the well-established cause. And so the available standard treatment options targets at relieving the spasm of the internal anal sphincter with surgical or chemical methods. Gold standard in the management of the Chronic fissure in ano is the time proven, Lateral Internal Sphincterotomy with healing rates above 95%. But the need for the alternative is always been there to overcome the surgical stress and risk of incontinence. Here we have different chemicals which do the same job of relaxing the tone of internal sphincter by their special properties. Of which, Diltazem, a calcium channel blocker with its unique profile of better healing rates and least side effects is

been used in its topical form locally. The present study has compared the healing rates of Chronic fissure in ano using 2%Topical Diltiazem with the Surgical Sphincterotomy. It also compares and analyses the other secondary objectives namely the recovery of Pain, Bleeding per Rectum, risk of Incontinence and the recurrence rates in both the methods.

With Results of the study we conclude that Chemical Sphincterotomy using 2% Topical Diltiazem is an effective alternative for the Gold standard Surgical Sphincterotomy and should be offered as a first line of treatment for the patients with chronic fissure in ano. Surgical sphincterotomy can be reserved for refractory cases alone considering its morbidity.

KEYWORDS

**Chronic Fissure In Ano, Chemical Sphincterotomy, 2%Topical Diltiazem, Surgical Sphincterotomy.**

# INTRODUCTION

Fissure in ano is the most common painful condition of perianal region, characterized by longitudinal ulcers affecting the distal part of the anal canal. It's so common that it affects 1 in 10 people and causes very disabling symptoms such as severe cutting type perianal pain & bleeding per rectum making the diseased to suffer intense mental & physical agony in spite of rest and analgesics. Also the chronic fissures behave more differently in that way they are more persistent and relapsing than the acute fissures which are self-healing.

Much has been already discussed in the literature regarding the aetiology of Fissures though the Persistent Hypertonia of the anal sphincters is claimed to be the well-established cause. And so the available standard treatment options targets at relieving the spasm of the internal anal sphincter with surgical or chemical methods. Gold standard in the management of the chronic fissure in ano is the time proven, Lateral Internal Sphincterotomy with healing rates above 95%. But the need for the alternative is always been there to overcome the surgical stress and risk of incontinence. There are different chemicals which do the same job of relaxing the tone of internal sphincter by their special

properties. Of which, Diltiazem, a calcium channel blocker with its unique profile of better healing rates and least side effects is been used in its topical form locally. Though many trials have already been done with 2 % Topical Diltiazem in management of chronic fissure in ano, less emphasis has been paid to its methodology, dosage and compliance of usage which may be the reason for its higher recurrence rates and lesser cure rates.

The present study has been designed keenly taking all these into consideration and it compares the healing rates of chronic anal fissures using 2% Diltiazem(Chemical sphincterotomy) with that of the gold standard Surgical Lateral Internal sphincterotomy (Surgical sphincterotomy) as the primary objective. It also compares and analyses the other secondary objectives namely the recovery of Pain, Bleeding per Rectum, risk of Incontinence and the recurrence rates in both the methods.

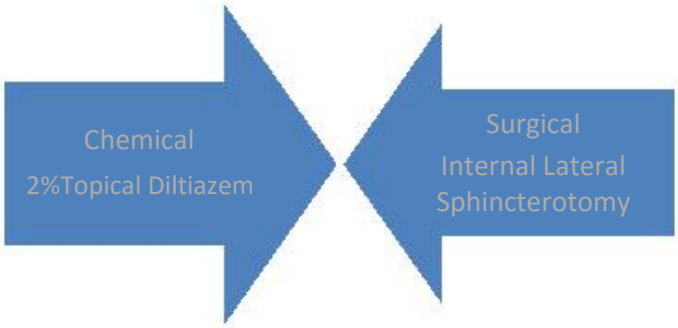



**Fig1.1 A Prospective Interventional Study between Chemical Sphincterotomy using 2%Topical Diltiazem And Surgical Internal Sphincterotomy in the management of Chronic Fissure in Ano.**

This clinical trial has been conducted in ESIC Medical College & PGIMSR, K.K. Nagar, Chennai-78, with the patients suffering from chronic fissure in ano attending the Surgical Outpatient Department. Ethical committee approval was obtained priorly as per protocol. Present Study includes 189 patients of chronic fissure in ano treated over a period of 18 months (Nov2013 to May 2015). Results has been analysed in both descriptive and statistical point of views and brought out in a simple understandable format for the readers.

**Discussion of this study has been done with the review of literature and appropriate references.**

# AIM OF THE STUDY

The primary aim of the study is to compare the efficacy of the 2%Topical Diltiazem with the Surgical Lateral Internal sphincterotomy in curing the chronic fissure in ano, which correlates directly with the Fissure healing rates.

The secondary objectives will be to compare the relief of other symptoms and morbid aspects of the treatment, as mentioned below

1. Recovery of Pain
2. Recovery of Bleeding per rectum
3. Recovery time
4. Risk of Anal Incontinence
5. Morbid aspects of Treatment.
6. Recurrence rate
7. Work resume time
8. Conversion rate.

# MATERIALS AND METHODS

The study was conducted as a clinical trial at ESIC medical college & PGIMSR, Chennai -78, during the period between November2013 to May 2015.

## SAMPLE AND SAMPLE SIZE DEFINITIONS

**Population:**

The Patients diagnosed to have chronic anal fissure attending the Surgery Out Patient Department (OPD) of ESIC Medical College & Hospital.

Diagnosis was based on history, clinical examination and Anoscopy (if tolerated by the patients).

History wise all patients had severe cutting type of pain during defecation & Bleeding per anum lasting for more than six weeks.

Clinical examination involved gentle separation of the buttocks and examination of the anus, to look for a linear ulcer in anoderm at the lower half of the anal canal with or without the sentinel pile.

**Inclusion criteria**

Consenting patients between 16 to 65 years of age with symptomatic chronic fissure in ano among the population were included in the study. Extremes of age were not included due to possibility of age related bias.

**Exclusion Criteria**

Patients with the following associated conditions were excluded from the study:

a. Pregnant/lactating women,

b. Inflammatory bowel disease, tuberculosis, malignancy and sexually transmitted diseases,

c. Prior anal surgery,

d. Previously Refractory to 2% Topical Diltiazem,

e. Associated haemorrhoids, fistula

f. Patients with significant cardiovascular diseases, &

g. Patients opting for Specific Treatment (Chemical/surgery).

**SAMPLE**

With the above mentioned selection and exclusion criteria, the appropriate Sample was drawn from the population.

**SAMPLE SIZE**

In this Prospective Interventional trial- Parallel Study Design involving two groups, Sample size was calculated to be 150, with 75 in each group.

**Formula:**

$N= Z^2 \{P1x (1-P1) + P2x (1-P2)\}/ (P1-P2)^2$

Z- Involves the Power and significance of alpha & beta errors Power was kept as 90% and p value significant at 0.05

P1- Assumed success rate in Group A

P2- Assumed success rate in Group B

It is observed from previous studies that the efficacy of Chemical Sphincterotomy using 2% tropical Diltiazem is about 80% and that of Surgical Internal Sphincterotomy is about 95%. To estimate the difference with 95% confidence level & 80% power the minimum sample required is about 75 per arm (total of 150 patients for two arms).

Based on this the sample size was calculated as 75 in each group with total of 150 patients. But the actual sample studied was 189 which is more than the needed volume.

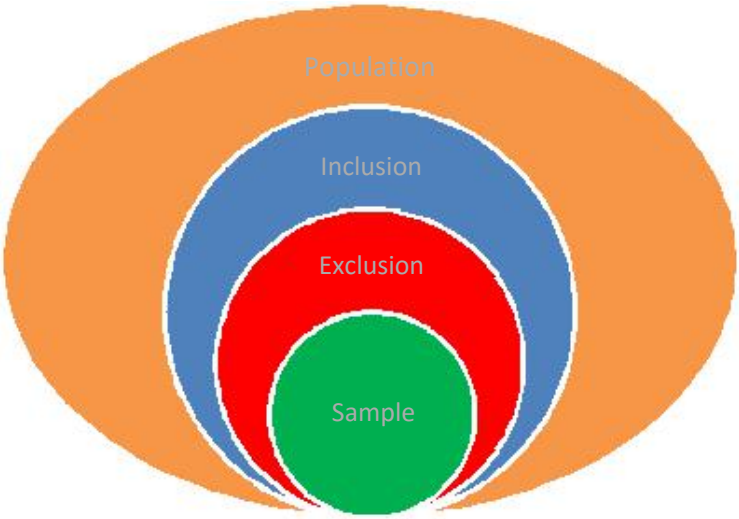



**Fig. 3.1 Selection of Sample.**

## SAMPLING METHOD

Total 189 patients with Chronic Anal Fissure attending Surgical Out Patient Department were enrolled in the study. Odd no of patients starting 1,3,5,…189 were assigned to group A, who received treatment with 2% Topical Diltiazem as outpatients and the remaining even no of patients starting from 2,4,6,….188 were assigned to group B (surgical sphincterotomy group). The B group patients were hospitalized for the surgery

## METHODOLOGY[1-10]

- The A group was treated with a 2% Diltiazem ointment (chemical sphincterotomy). The subjects were specially taught to apply the ointment (about a size of 1.5cm) to the anoderm thrice daily for 6 consecutive weeks with proper hygiene and technique. (Using clean washed hands before and after application, nails proper trimmed to avoid trauma)

- In present Study the 2% Topical Diltiazem ointment was used.. Each tube weighed 30g and the dosage prescribed was 1.5cm for three times a day, measured in a small scale given with the ointment. It was found that each 30g tube on milking came up to 124.5cm length. The daily maximum requirement per day was 1.5 x 3= 4.5cm, and that for 6weeks (42 days) was 42 x 4.5 = 189 cm. So on an average 2 tubes were required for each patient to complete the course of the treatment. The cost of each tube was around 100 rupees, so the total cost of the treatment was 200 rupees only.


**Figure 3.2 DILTIAZEM GEL 2%**

* The cases from the B group underwent open lateral internal sphincterotomy under spinal/general anaesthesia as inpatient in the hospital. In open method incision was made directly across the intersphincteric groove and the sphincter muscles are separated from the anal mucosa and then divided. The cost of the procedure could not be measured because in our setup the medical treatment was free of cost for the insured patients.

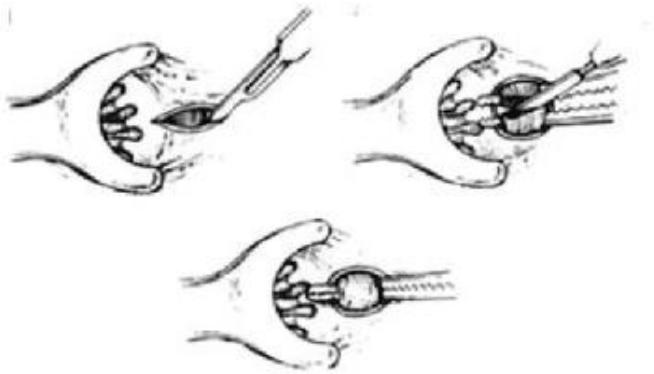


**Fig3.3 Surgical sphincterotomy**

- During the course of the treatment, both the groups were asked to eat a high fibre diet, use warm Seitz baths, mild analgesics & laxatives.

- The patients were reviewed in the Outpatients Department at the 2nd, 4th, 6th, 8th & 10th weekends during the course of the treatment.

- At each visit, details on the fissure healing, pain relief and any side effects and recurrence was documented.

- Also, specific questions were asked regarding the leakage of flatus and faeces. Incontinence was calculated based on Wexner's score.[Table3.1]

| | *Frequency* | | | | |
|---|---|---|---|---|---|
| ***Type of incontinence*** | ***Never*** | ***Rarely*** | ***Sometimes*** | ***Usually*** | ***Always*** |
| Solid | 0 | 1 | 2 | 3 | 4 |
| Liquid | 0 | 1 | 2 | 3 | 4 |
| Gas | 0 | 1 | 2 | 3 | 4 |
| Wears pad | 0 | 1 | 2 | 3 | 4 |
| Lifestyle alteration | 0 | 1 | 2 | 3 | 4 |

**Table 3.1 Wexner incontinence score**

0 - Perfect continence; 1-7 - Good continence

8-14 Moderate incontinence 15-20 severe incontinence

- The healing of the fissure was assessed visually. Healing was defined as the complete disappearance of the fissure on examination

- The intensity of Pain was assessed by Visual Analogue Score.

- Every patient was supplied with a pain score chart [fig3.4]. They were instructed to mark the level of the pain in it daily. These charts were graded from 0 to 10 and marked at one end-0 (no pain) and at the other end -10 (worst pain). 1-3(mild pain), 4-7(moderate pain), 8-10(severe pain). Our target was to achieve a pain score less than 3, preferably near 0.

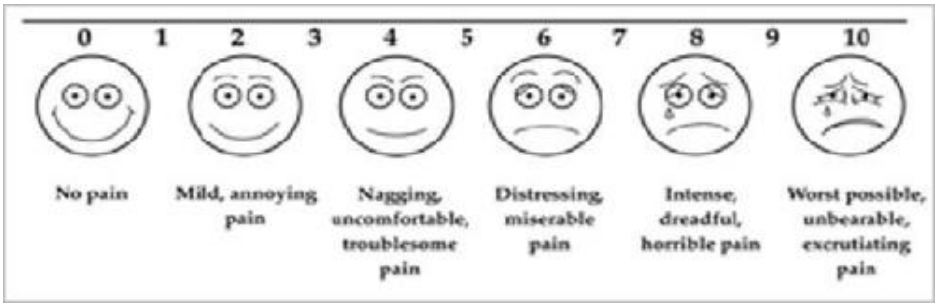



**Fig. 3.4 Visual analogue Pain scoring chart**

- Bleeding per rectum was also graded into the Following

0- Nil bleeding
1- Occasional blood spotting in stools (<1/week) [Minimal]
2- Blood stained stools [Mild]
3- Frank blood in stools [Moderate]
4- Blood clots passing per rectum [Severe].

- Work resume time was defined as the time required by the patients for symptomatic pain relief and to resume with Daily routine work. It was calculated in weeks.

- Recovery time was defined as the time taken for complete healing of the fissure. It was calculated in weeks.

- The disease was considered as recurrent if the fissure reappeared at the same site after 2 months of surgery or 6 weeks therapy of 2%Diltiazem.

- Drop outs were those patients who are quitting the trial before completion of 10 weeks/those who are switching over to other alternative methods before 10 weeks.

- Patients of Study Group A who have completed 10 weeks of follow up and found refractory to treatment were allowed to switch over to Surgical method and observed. They were considered as Failure cases of Group A. Similarly group B patients refractory to surgical treatment were allowed to convert to Chemical sphincterotomy as per the patients consent. But the data was not analysed within the Groups A or B of this study, but was included in the Conversion rate.

14 Screening Procedures / Visits**:** The subjects underwent clinical examination which included visual & digital Rectal Examination, a proctoscopic examination & fill up questionnaire.

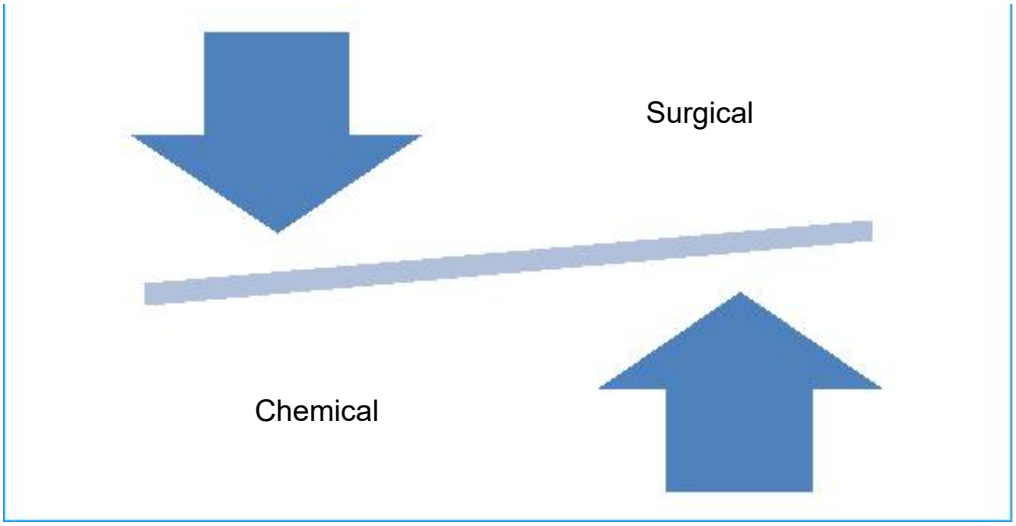



**Fig 3.5 Assessment of Chemical & Surgical Methods**

# ANALYSIS

Assessments of following Parameters were made.

**PRIMARY:** Fissure Healing Rate

**SECONDARY:**

a. Recovery of Pain

b. Recovery of Bleeding per rectum

c. Recovery time

d. Risk of Anal Incontinence

e. Morbid aspects of the treatment

f. Recurrence rate

g. Work resume time

h. Conversion rate.

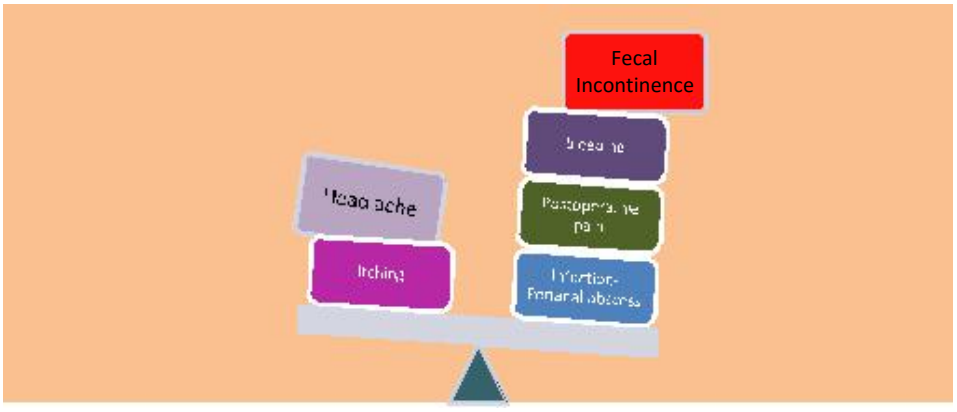
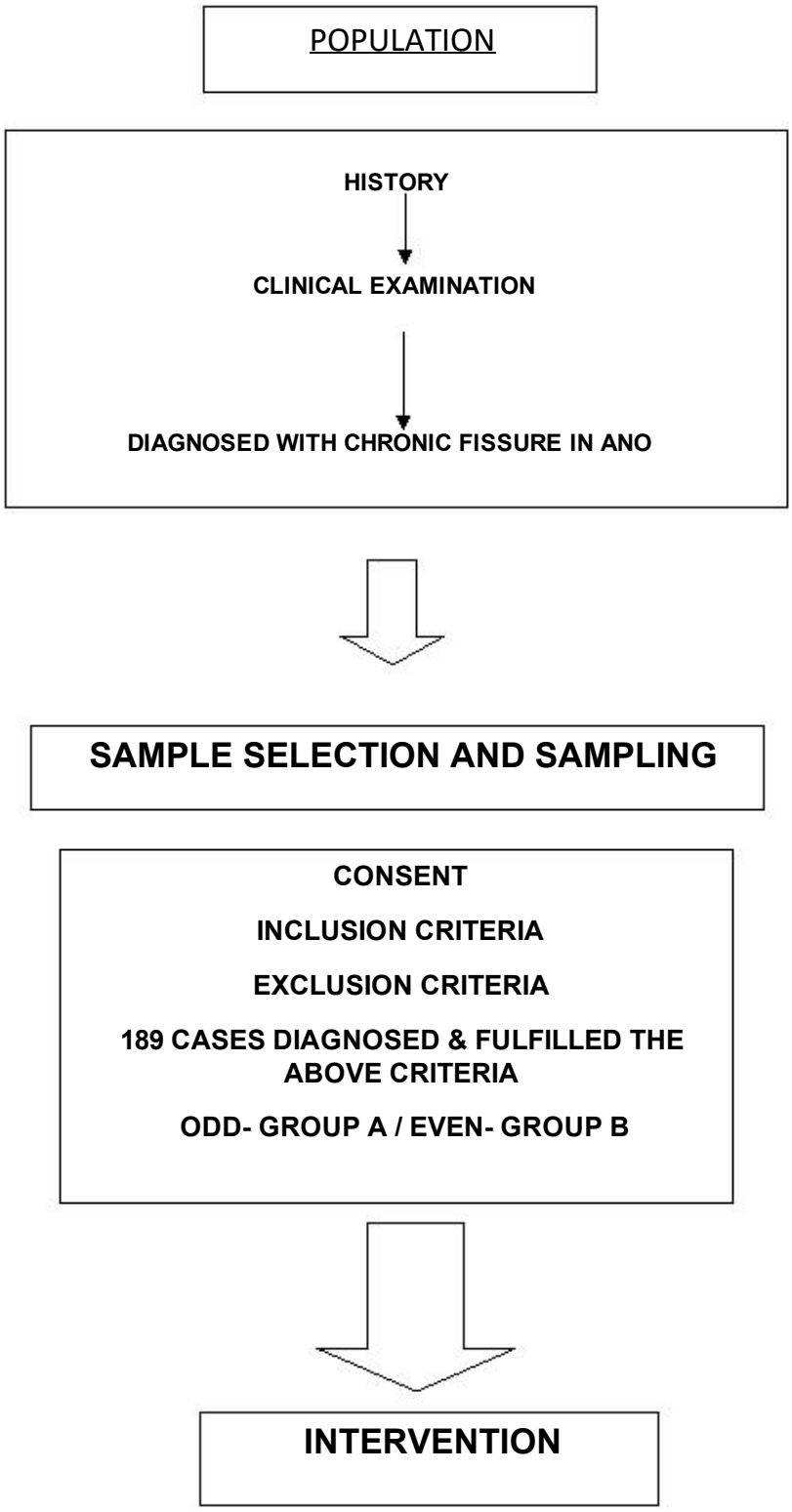
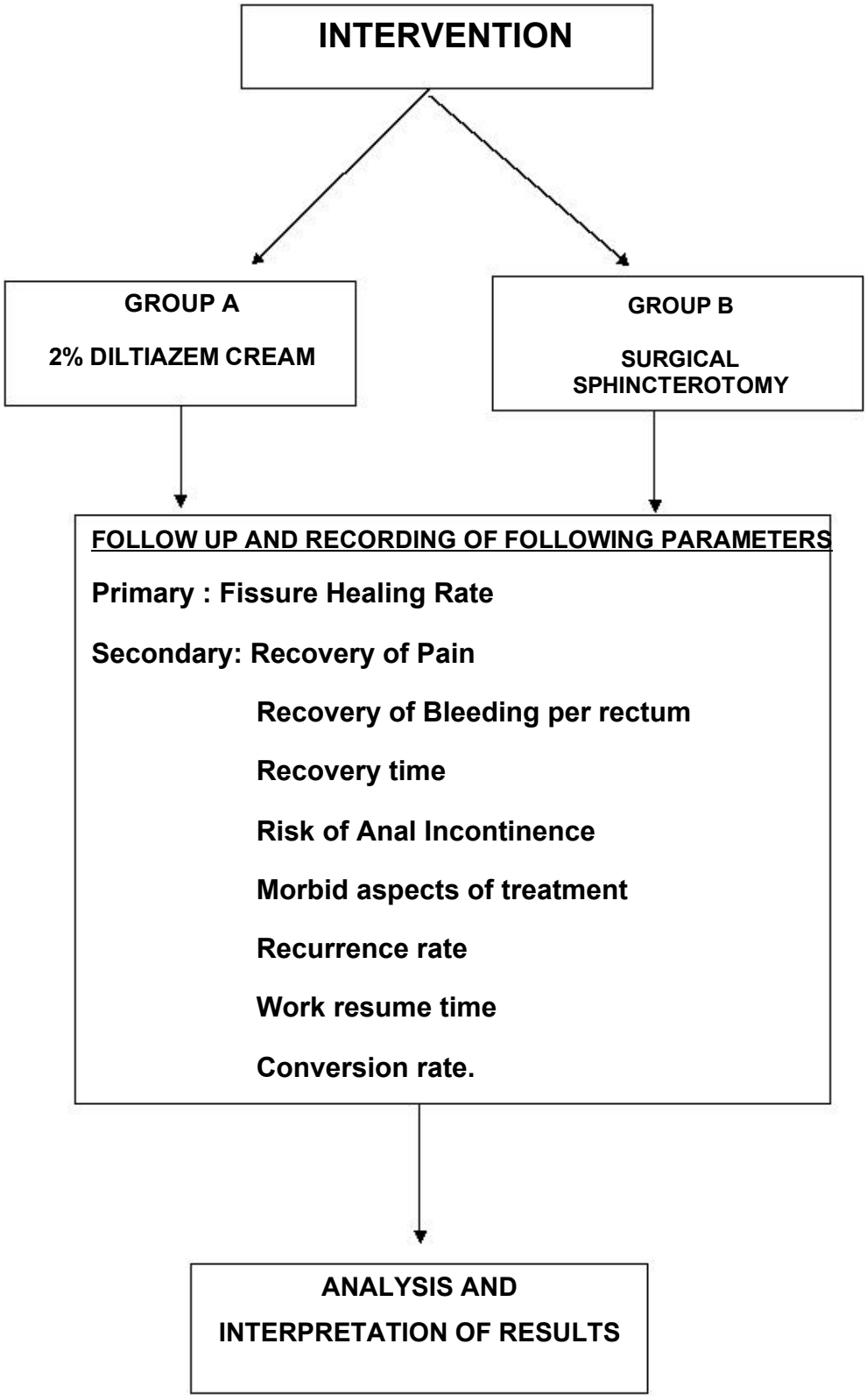



**Fig. 3.6 Adverse effects of the treatment**


POPULATION
HISTORY
CLINICAL EXAMINATION
DIAGNOSED WITH CHRONIC FISSURE IN ANO
SAMPLE SELECTION AND SAMPLING
CONSENT
INCLUSION CRITERIA
EXCLUSION CRITERIA
189 CASES DIAGNOSED & FULFILLED THE ABOVE CRITERIA
ODD- GROUP A / EVEN- GROUP B
INTERVENTION


INTERVENTION
GROUP A
2% DILTIAZEM CREAM
GROUP B
SURGICAL SPHINCTEROTOMY
FOLLOW UP AND RECORDING OF FOLLOWING PARAMETERS
Primary : Fissure Healing Rate
Secondary: Recovery of Pain
Recovery of Bleeding per rectum
Recovery time
Risk of Anal Incontinence
Morbid aspects of treatment
Recurrence rate
Work resume time
Conversion rate.
ANALYSIS AND INTERPRETATION OF RESULTS

# REVIEW OF LITERATURE

Anal Fissure is a painful tear or crack in the skin or the lining of the lower third of Anal Canal. It is a longitudinal ulcer extending from the surface epithelium usually exposing the core sphincter muscle. It can occur in any age& gender with an incidence of 1 in 10 people being affected at some time of their life. Classically presents with severe cutting pain during bowel movements with bright red streaky bleed. Most of the time, it is a self-limiting condition where healing occurs in few days**.** But with the intensity and duration with which it presents, it can be classified as Acute and Chronic anal fissures.

## Downside of Upright posture

By evolution, Human race have transformed into a bipedal upright organism. It has been nearly 400 million years already since this transformation but Human race couldn't completely adapt to this and facing various disorders such as knee & back arthritis, strain full defecation leading to Haemorrhoids and Fissures in Anus.

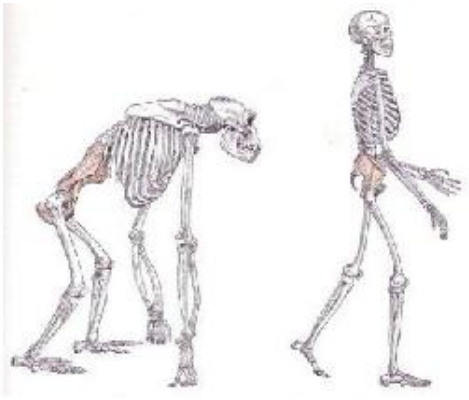


**Fig 4.1 Evolution of Man into Upright posture**

## Anal canal Gross Anatomy

Anal canal is the most terminal part of the large intestine extending from the Anal verge (Anal orifice) below to the Rectum above. It is about 4cm in length and could be divided into 3 distinct regions. Described from below as it is usually examined in that manner, they are the Anoderm , Anal pecten & Anal mucosa.

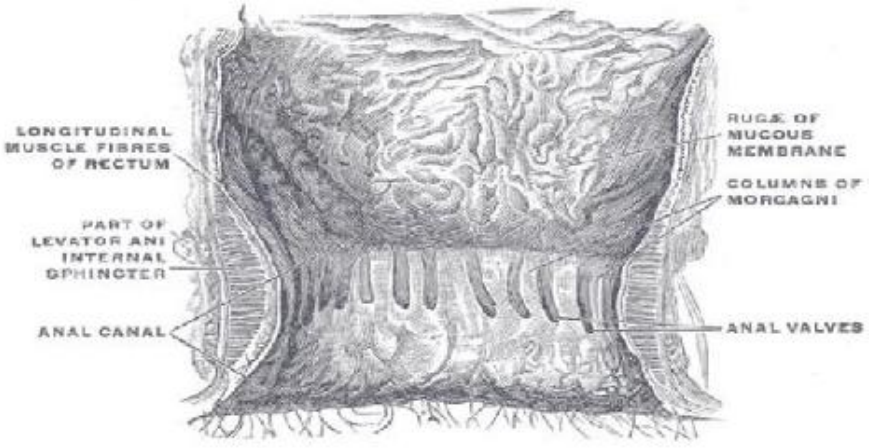



**Fig. 4.2 Anal Canal Anatomy**

20 Anal canal extends from Anal verge (transition area between perianal skin and anal canal) to the Anorectal ring formed by the Puborectalis sling causing anteriosuperior pull. Now this passage is divided into upper 2/3$^{rd}$ and lower 1/3$^{rd}$ by the Pectinate or Dentate line marked by the scalloping of the Anal valves circumferentially. It represents the embryonic transition zone between the Proctodeum below and the Postallantoic Gut above. The upper part is lined by simple columnar epithelium is the Anal Mucosa region (Zona Columnaris) and it is insensitive to pain, supplied by autonomic plexus. It contains the longitudinal folds of Anal columns with prominent ones at Left lateral, Right anterior and Posterior corresponding to 3, 7&11'o' clock positions forming the Anal cushions (common sites of internal haemorrhoids). These columns end in Anal valves above which the Anal glands open into Anal crypts or Sinuses (foci of infection in Perianal Abscess). Now just below the Pectinate line for about 1-2 cm is the Anal Pecten or Actual Transition zone (Zona Hemorrhagica) lined by simple non keratinized squamous epithelium. Lower border of this is marked by the White line of Hilton, a broad watershed line. Below this is the Anal canal lined by Keratinized Squamous epithelium lacking Skin appendages, called as Anoderm (Zona cutanea). This region is rightly called Anoderm as it appears like skin, it is keratinized & it is pain sensitive and supplied by inferior rectal nerve, branch of Internal

Pudendal Nerve. Anal fissures involve this part of Anal canal.

| Anatomical distribution | Anal canal upper 2/3rd | Anal canal lower 1/3rd |
|---|---|---|
| Embryological Origin | Endoderm | Ectoderm |
| Blood supply | Superior Rectal artery (Portal) | Inferior Rectal artery (Systemic) |
| Lymphatics | Sacral & Internal Iliac nodes | Superficial Inguinal nodes |
| Nerve supply | Autonomic Plexus (Pain Insensitive) | Inferior rectal branch of Internal Pudendal Nerve(Pain Sensitive) |
| Epithelium | Columnar | Stratified Squamous |
| Haemorrhoids | Internal | External |

**Table. 4.1 Anal Canal anatomy**

**Embryology**[41]

Hind gut opens into the posterior part of Cloaca forming the upper part of Anal canal and the Ectoderm of Proctodeum (Anal Membrane) invaginates forming Anal pit, giving rise to lower part of Anal Canal. Subsequent degeneration of the Anal membrane establishes the continuity of the passage.

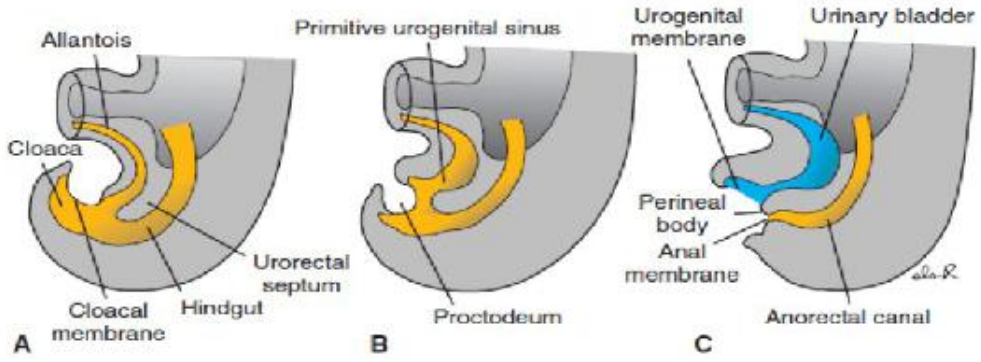



**Fig. 4.3 Development of Anal Canal**

## Sphincters of Anal Canal

There are two sphincter complexes in the Anal canal. They are the Internal and the External sphincters. Internal sphincter is an involuntary smooth muscle sphincter derived from the circular Muscles of the Rectum. External sphincter is a voluntary skeletal muscle complex.

Internal Anal Sphincter-IAS

It is about 5mm thick formed by the aggregation of the involuntary outer circular muscle fibres of Rectum. It extends about 2.5 to 4 cm in length. It is in a state of continuous contraction and contributes to 55% of resting pressure of Anal canal. It is very important for Anal continence especially for liquid and gas. Normally IAS is relaxed by Recto anal inhibitory reflex (RAIR) by the faecal distension of rectum, allowing the defecation.

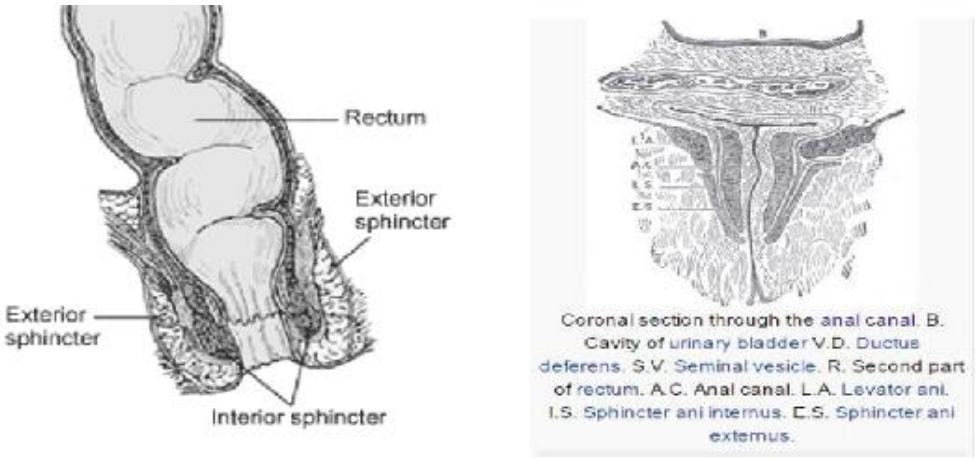



**Fig. 4.4 Sphincters of Anal Canal**

## External Sphincter

The classical description of the External sphincter gives it 3 parts i.e., Subcutaneous, Superficial and the Deep parts. But the newer description of External Anal sphincter is that it has got only 2 parts, they are the Superficial and the Deep parts. In this Model, Deep part comprises of fusion of Puborectalis and the Deep part of the Classical model and the Superficial Part is comprised of the Superficial and Subcutaneous Parts of the Classical Model. The Newer Model has more clinical relevance than the classical one and tallies with the MRI imaging appearance.

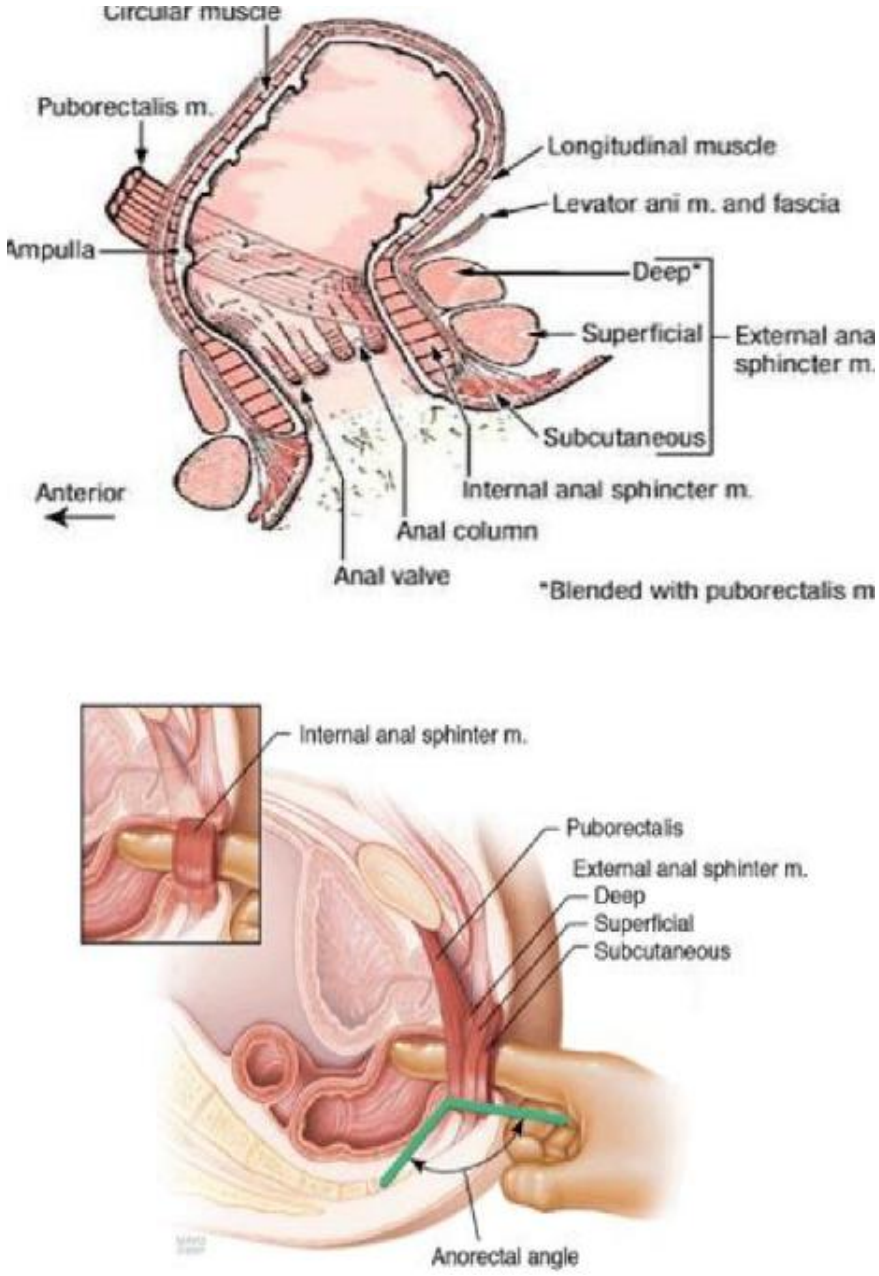



**Fig 4.5 External Sphincter components**

**FISSURE IN ANO**[10]

A tear in the Anal canal between the dentate (Pectinate) line and the Anal verge is described as Anal Fissure. It was first recognized as a disease by 1934**.** The claimed incidence is 1 in 350; affecting both sexes equally and even the children. Most commonly affecting the working population i.e. 15 to 40 yrs of age.

**Classification**

∑ ACUTE ANAL FISSURE

∑ CHRONIC ANAL FISSURE

**ACUTE ANAL FISSURE**

Acute Anal Fissure is defined as a new onset fissure in ano which is extremely painful and usually resolves spontaneously within a period of 6 weeks.

**CHRONIC FISSURE IN ANO**

Chronic Fissure is the one persisting for more than 6 weeks with characteristic features suggesting chronicity of the inflammation and non- healing nature of the ulcer.

A chronic fissure may have one or all of the following features

1. Due to the chronicity of the ulceration the internal sphincter fibres may be exposed at the base of the ulcer.

2. A Skin Tag may be seen at the distal margin of the Fissure, called as the Sentinel pile.

3. At the proximal end there is the Hypertrophied Anal Papilla

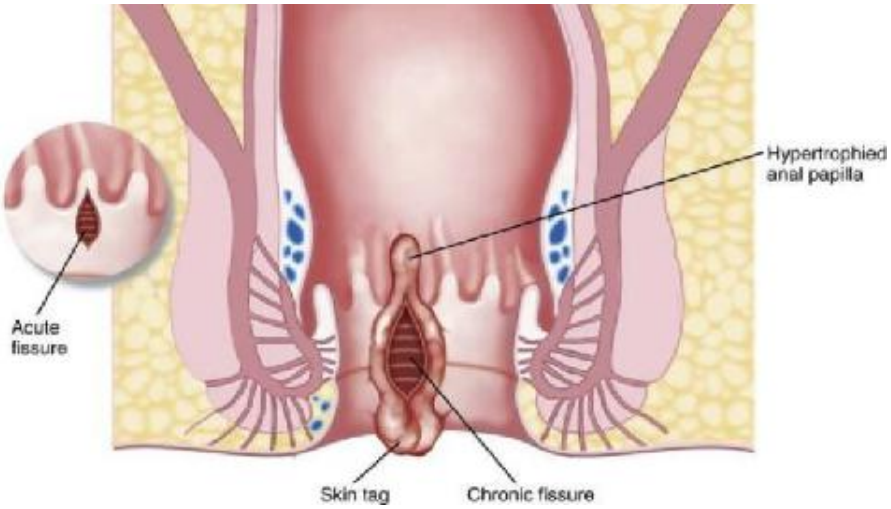



**Fig 4.6 Acute and Chronic Anal Fissures**

## Symptoms

∑ Severe Sharp Cutting type of Pain with each bowel Movement followed by Burning type of Pain which lasts for hours. Patients describe the pain as ‘passage of broken Glasses’

∑ Bright red bleed per rectum usually as linear streaks.

**Pathophysiology**

The exact cause of Anal fissure is yet a subject of debate. Conventionally it has been claimed that Mechanical trauma due to passage of stools is the cause of Fissures. But it has been reported that only 20% of people had the predisposing constipation history [2]. Internal Anal sphincter Hypertonia has proved to be the main culprit in formation and propagation of the Fissures. It has been thought for a very long time that this internal sphincter hypertonia was secondary to local trauma caused by passage of hard stools. Then this scenario keeps on repeating as the increased tone of the sphincters lead to further constipation and then constipation again causes local trauma during defecation, forming a vicious cycle [70]. Internal sphincter hypertonia keeps the resting pressure of anal canal above 90mm of Hg thereby jeopardizing the blood flow of the anal canal as the mean arteriolar pressure of the anal canal is around 85mm of Hg. In that posterior midline is affected the most which is supplied by end arteries and that these arteries pass through the internal sphincter before reaching the posterior midline. The reduction in posterior anodermal blood flow was documented by Doppler Flow study [13, 15]. It has also been found out that pain doesn't propagate the sphincter spasm as demonstrated by the persistent Hypertonia of the sphincter muscles even with the use of topical anaesthesia [16].

Numerous studies and theories have been put forth in this accord.

One of the Studies (Lund) established that the Decreased Nitric Oxide synthesis is reason for perpetuating the Fissure by increasing the Sphincter Tone. Actually Fissures are ischemic ulcers with the combination of raised tone of Internal anal sphincter and reduced Anodermal blood supply (Schouten et al study) commonly occurring in the Midline. And of that Posterior Midline is the most poorly perfused area of the anal canal accounting for about 90% Anal Fissures. Anterior fissure accounting for less than 10% and 2% will have both Anterior and Posterior Fissures. Fissures occurring off the midline should raise suspicion on the aetiology. They may be due to Infective (Sexually transmitted infections, AIDS) or Inflammatory (Crohn's disease, Ulcerative Colitis) or neoplastic pathologies.

Thus most modalities of treatment focus on relaxing or releasing the Internal anal sphincter spasm. This is because Hypertonia of Internal Anal sphincter remains the centre in vicious cycle of fissure propagation. Options range from topical ointments to surgical sphincterotomies. And the other adjuvants used in the treatment are the stool softeners, Laxatives, seitz bath and topical analgesics which give symptomatic relief.

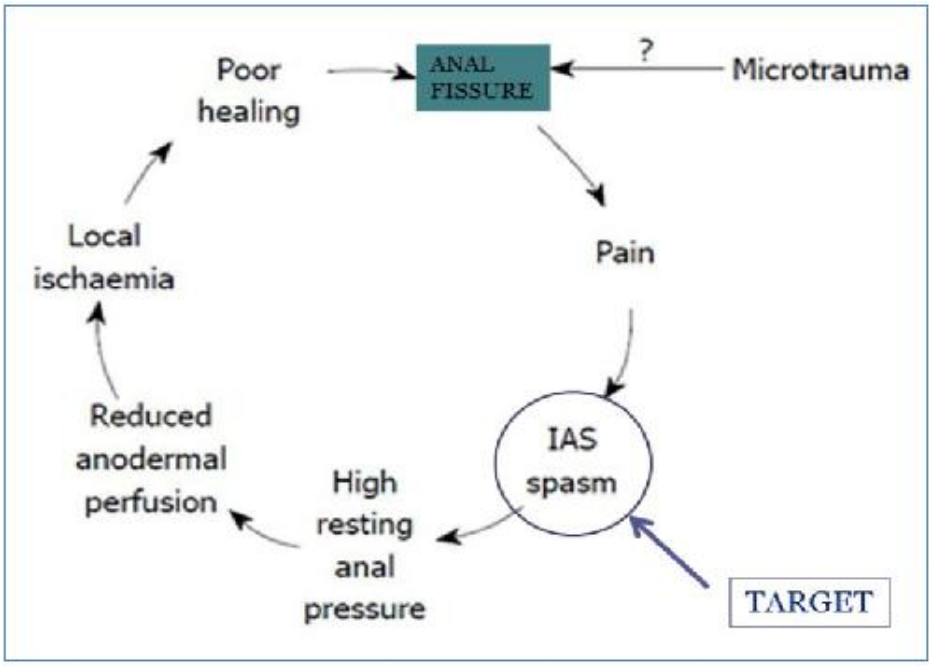



**Fig. 4.7 Vicious Cycle in the Pathophysiology of Anal Fissures.**

## Treatment Strategies

It can be broadly divided as Surgical and Medical.

## SURGICAL

### Lord's Manual Dilatation

The original Lords anal dilatation was described by Lord in 1838[26] and was popularly used in the haemorrhoids surgery. The concept was that under Anaesthesia manual pressure is applied to internal sphincter to stretch the fibres and release the spasm. The original procedure was done using 8 fingers then modified into gentler 4 finger technique [28]. Nielsen Et al using endoanal ultrasound showed that the dilatation leaded to irregular tears to both internal & external anal sphincters causing faecal incontinence [36]. Faecal incontinence rate was 24.3% [32]. Therefore due to the damage caused to the sphincter and the resultant post-operative Incontinence, it has been avoided

nowadays [33].

**Fig 4.8 LORD'S ANAL DILATATION**

**Pneumatic Balloon Dilatation**

To standardise the procedure of anal dilatation, dilatation was done with the Parks retractor opening up to 4.8cm with a 40mm recto sigmoid balloon. Similar to the Lords, here pneumatic Balloon pressure is used to stretch the sphincter with slightly lower incidence of faecal incontinence [29].

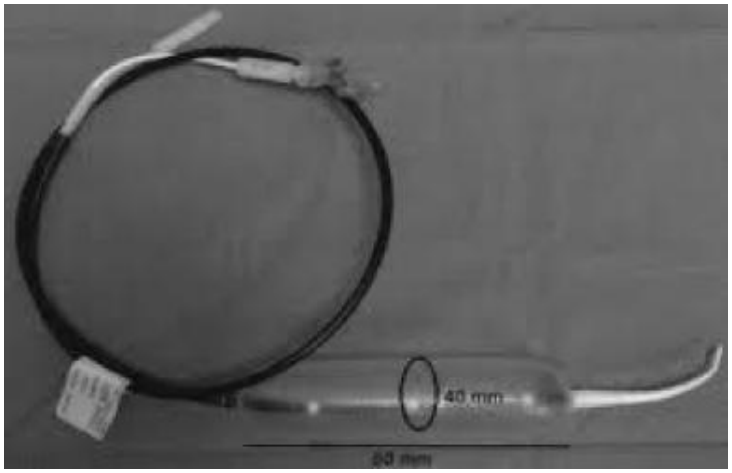



**Fig 4.9 Pneumatic Rectal Dilator.**

**Fissurectomy**

Surgical technique involves simple excision of the Fissure along with its indurated base including the skin tag. The resultant raw area can be left open are closed with various options such as primary suturing , Y- V advancement flaps etc. The raw area when left open leads to key hole deformity.

### Anorectal Advancement Flap

With Fissurec-tomy the resultant defect in anal mucosa is closed by a Y-V advancement flap reducing the side effects of key hole deformity.

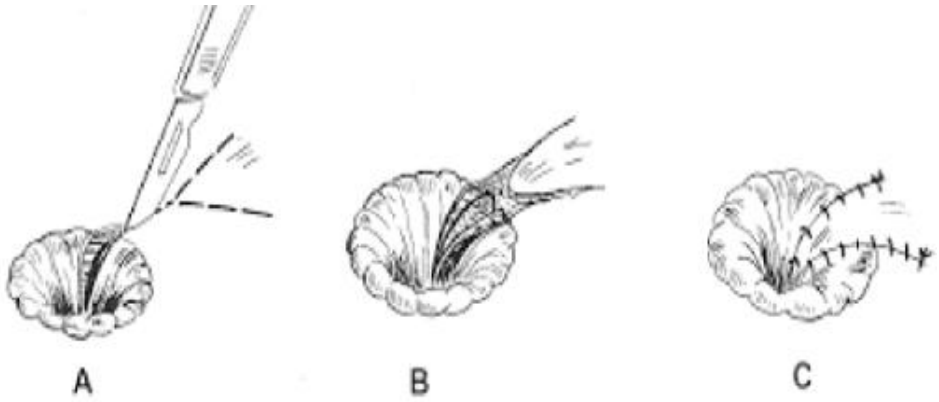



**Fig 4.10 Y- V Advancement Flap Used In Fissure Healing**

## SPHINCTEROTOMY[17,18,19,20,24,25]

### Posterior Sphincterotomy

Introduced by Eisenheimer in 1951, involves the division of the Internal sphincter fibres at Posterior midline up to the Dentate line. It has replaced by the Lateral Sphincterotomy due to the adverse effects such as Keyhole defect and frequent Faecal soiling.

**Lateral Sphincterotomy**

It is the Gold standard in the treatment care of fissure in ano with over 96% cure rates. This method was again putforth by Eisenheimer in 1951 and was modified by Notaras (1969). It involves division of the Internal sphincter along the 3/9 ‘o’clock positions having better cure rates and less chances of Incontinence (<10%). There are two methods described in it, the Open and Closed Methods. In Open method incision is made directly across the intersphincteric groove and the sphincter muscles are separated from the anal mucosa and then divided. The Closed technique is a Subcutaneous technique starting with a small incision at the intersphincteric groove then inserting a scalpel with the blade parallel to the internal sphincter, advancing it along the intersphincteric groove and rotating the scalpel towards the internal sphincter and dividing it.

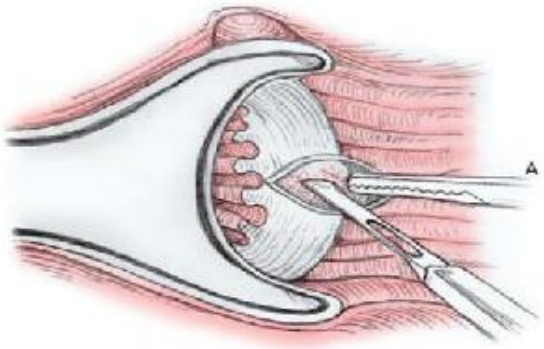



**Fig 4.11 Open Lateral Sphincterotomy**

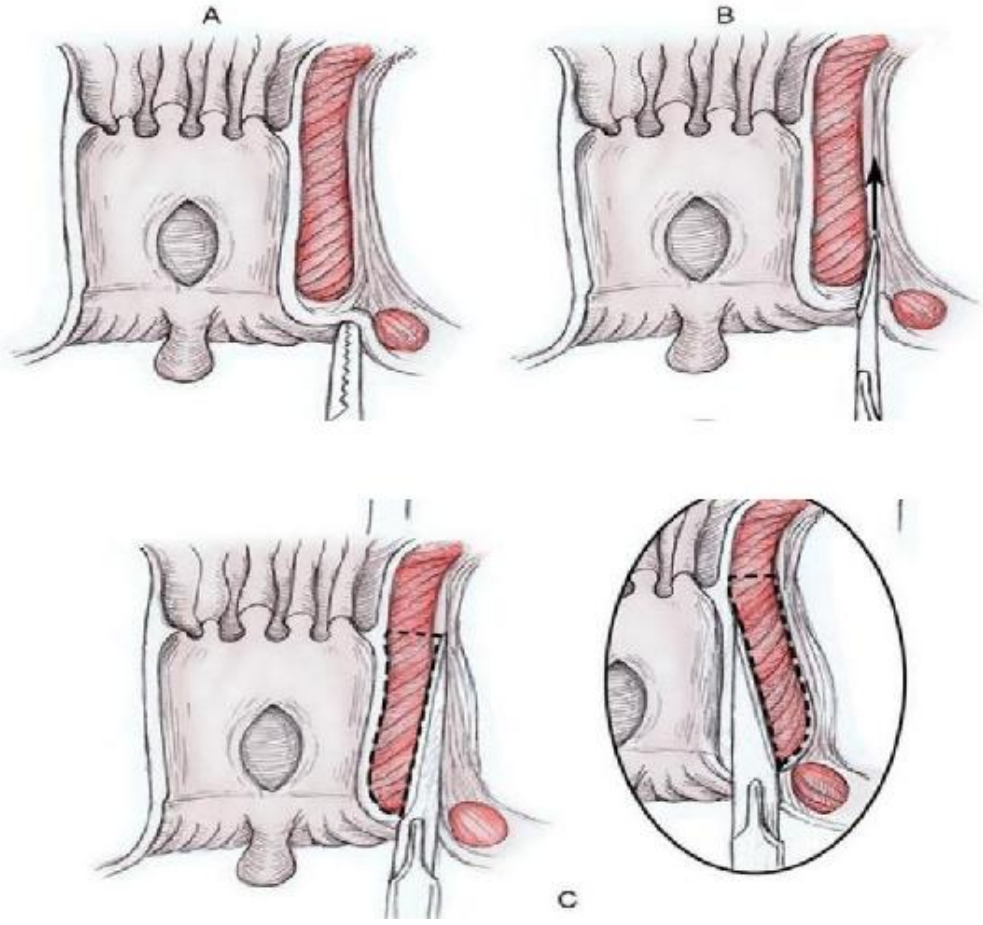



**Fig 4.12 Closed Lateral Sphincterotomy in steps.**

## MEDICAL MANAGEMENT

Non-surgical methods are usually used as the first line of therapy for Fissure in ano. It includes modalities ranging from High fibre diet, stool softeners, Warm sitz bath, topical Analgesics & Chemical Sphincterotomies. All aimed at preventing constipation & hard stool movements, reducing the pain & the spasm of the Internal Sphincter.

### I. Chemical cauterization:

This is done by using silver nitrate or phenol-in-glycerine. This procedure may be repeated a couple of times until healing occur. It takes about 4 to 8 weeks for complete healing of the fissure.

**Drawbacks:**

The toxicity of the drugs, accidental injection in the surrounding tissue amounting to general poisoning, hematoma and infection reported had refrain the surgeons from regularly resorting to this method.

### II. Chemical sphincterotomy using Nitric Oxide Donors:[38-40]

Nitric oxide is an important neurotransmitter of Non adrenergic – Non cholinergic nerve endings of gut mediating internal anal sphincter relaxation. It has been proved that chronic anal fissure is ischemic in

origin due to poor blood supply and spasm of internal anal sphincter. Nitric oxide donors such as glycerly trinitrate [GTN] or Isosorbide di nitrate are known to cause a chemical sphincterotomy leading to healing of fissure. A 2% GTN ointment applied twice to the anoderm for 6 weeks have given a success rate of 68% on an average [43].

**Drawbacks-**

However, during the course of therapy, strict dietary restrictions to smoothen the stool are necessary. Headache during therapy is a major concern with the incidence as high as 20– 100%. Though the application of GTN has a high healing rate; it also has a high recurrence rate.

## III. Injection of Botulinum Toxin [52-59]

Botulinum toxins A, B, and E specifically cleave SNARE Proteins, preventing "neurosecretory vesicles" from docking/fusing with the interior surface of the plasma membrane of the nerve synapse, and so block release of neurotransmitter. In inhibiting acetylcholine release, nerve impulses are blocked, causing the flaccid (sagging) paralysis of muscles. A 20 Units of type A botulinum toxin [Botox] is injected bilaterally (10 units each side) to the fissure. The toxin exerts its effects on the acetylcholine releasing presynaptic parasympathetic peripheral

nerve endings as well as the ganglionic nerve endings, thereby leading to flaccid paralysis of the internal sphincter.

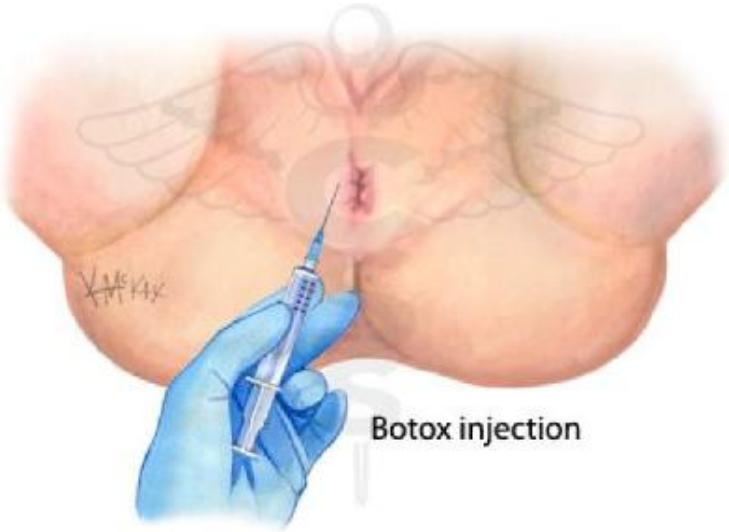



**Fig 4.13 Botox Injection**

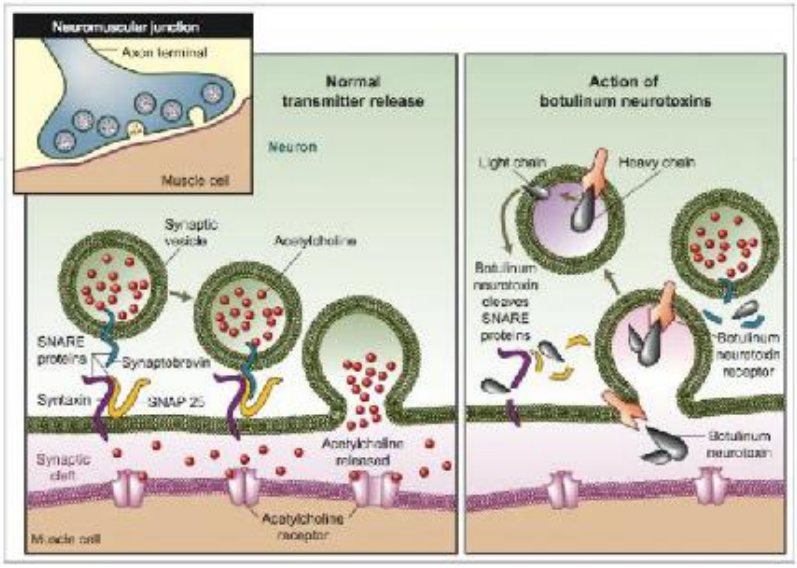



**Fig4.14 Mechanism of Botulinium toxin**

38 This causes sphincter paresis for about 3 months, a period which is sufficient for healing of a chronic non-complicated [not associated

with sentinel tag, internal haemorrhoids, anal polyps or post fissure fistula] fissure. It is well tolerated and can be administered on an outpatient basis. The healing rate reported is about 69-79%.

**IV. Chemical sphincterotomy with Calcium Antagonists.[60-63]**

Nifedipine is an L-type calcium channel antagonist. L-type Calcium channels are the principal Calcium channels in the GI smooth muscles. In the treatment of anal fissures, 20 mg of Nifedipine is given twice daily. Nifedipine is found effective in relieving the sphincter spasm there by allowing faster healing.

**Drawback:**

It is, however, supposed to cause reversible internal anal sphincterolysis. Most of these drugs have a short duration of action and need to be administered 2–3 times daily. Similarly, side effects like headache, palpitations, flushing, dizziness, colicky abdominal pain; ankle oedema, reduced taste and smell, nausea and diplopia have been reported

**Chemical Sphincterotomy with Diltiazem**:

Diltiazem is a NonDihydropyridines (Non-DHP) Calcium channel blocker used in the treatment of hypertension, angina pectoris, and some types of arrhythmia (Type IV antiarrhythmic drug). It relaxes the smooth muscles in the walls of arteries, which opens (dilates) the arteries, allows blood to flow more easily, and lowers blood pressure. Diltiazem is also being used in the treatment of anal fissures. It can be taken orally or applied topically with increased effectiveness.When applied topically, it is made into a cream form using either vaseline or Phlojel. Phlojel absorbs the diltiazem into the problem area better than the vaseline base. It has good short term success rates. Topically it is used as 2% gel over the anoderm. It decreases the tone of the Internal Anal sphincter and increases the blood supply of the region, thereby augmenting the Fissure healing. The results are comparable to Glyceryl trinitrate and also with better tolerability. These parameters have pushed to do many trials to establish the efficacy and tolerability in comparison to other modalities.

| | |
|---|---|
| Mechanism of Action | ➢ Calcium channel blocker<br>▪ Relaxes the internal anal sphincter, reducing pain and increasing tissue blood flow |
| Preclinical Safety | ➢ Preclinical topical safety with 2% Diltiazem twice daily for ninety days |
| Clinical Pharmacology | ➢ Topical has < 10% systemic exposure as oral dose but significantly greater effect on sphincter tone – i.e., blood levels do not predict activity. Low exposure = better tolerability than oral Diltiazem |
| Clinical Data | ➢ Ten clinical trials in 453 individuals<br>➢ Similar or better reduction in pain, significantly better tolerability than GTN |

**Table. 4.2 Topical Diltiazem in Chemical Sphincterotomy.**

There are several trials done to compare the efficacy and morbidity of 2% topical Diltiazem in the management of chronic fissure in ano. Recent studies suggest that it could be used as a first line of medical management and surgery could be reserved for non-responders.

In Rithin Suvarna et al trial, 2012(JCDR/2012/4386:000) they compared the Diltiazem2% topical ointment with that of the gold standard, Surgical Internal Sphincterotomy. It was a prospective trial with 100 patients in each group. The end result was that complete fissure healing was found better in surgical (95.87%) than the chemical group (69.23%). And also recurrence rate was 10.43% with Chemical Sphincterotomy whereas it was nil with Surgery. But chemical method had very little incidence of anal incontinence. The trial recommends the use of 2% Diltiazem as first line of treatment in chronic fissures.

41 In Majid Aziz et al trial (Journal of Surgery Pakistan (International) 17 (1) January - March 2012) involving total of 60 patients with 30 in each group, showed that the healing rate of 2% diltiazem(33.33%) was very less compared to that of Lateral internal sphincterotomy(96.66%.) not favouring the use of chemical sphincterotomy.

In Giridhar C. M et al trial(J Clin Diagn Res. 2014 Oct; 8(10): NC01–NC02.) again compared the chemical with surgical sphincterotomy. The healing rates with 2% diltiazem was reported to better i.e 88.46% with mean healing time of 5.04 weeks. Which again suggests that chemical sphincterotomy can be used as the first line of management.

In another study by Rithin Suvarna et al, 2%topical diltiazem was compared with that of 0.2% topical glyceryl trinitrate(GTN) in the management of chronic fissure in ano. Healing rate with topical Diltiazem (71.87%) was better than GTN (68.23%) with p value of 0.0001, making it statistically significant. Also the major adverse effect was headache in both groups but with much lesser incidence in Diltiazem group (5.2% vs. 67%). Recurrence rate was also low in Diltiazem group (9.67% vs. 19.56%) suggesting that the topical Diltiazem was a better chemical agent with higher efficacy and lesser morbidity.

42 With all the available data it has been proposed that the Chemical sphincteromy can be offered as the first line of treatment in chronic fissure in ano avoiding the hospitalization and the morbidity (faecal incontinence) of the surgical method. Among the available options Chemical sphincterotomy using topical 2% Diltiazem is been considered to be the most safe, simple, cost effective, efficacious method. So 2% topical Diltiazem can be used as the first line of management of chronic fissures leaving surgical sphincteromy reserved for only the non-responders.

# STATISTICAL ANALYSIS

## STUDY DEMOGRAPHY

The study involved 189 patients diagnosed with Chronic fissure in ano attending the Surgery OPD, ESIC Medical college & PGIMSR, Chennai-78. Of which 6 were dropouts, who lost follow-up during the study period. Excluding the dropouts the final sample was 183 patients with 90 in Group A and 93 in Group B.

## AGE DISTRIBUTION

Age distribution of the Sample population ranged from 16 to 64 years, with an average age of 37 years.

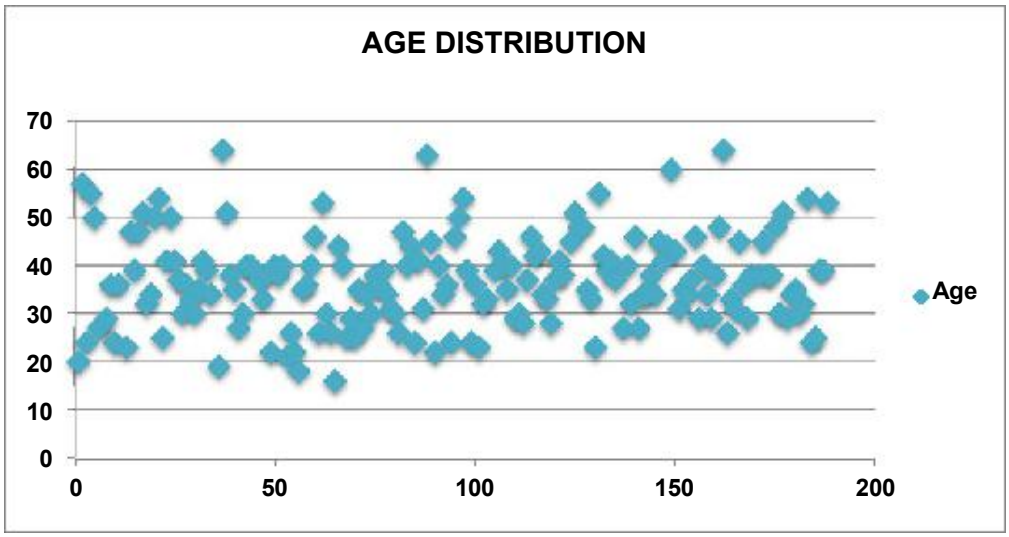



**Figure 5.1 Age Distribution Of The Sample**

## GENDER RATIO

Females outnumbered the male subjects with the ratio of 5:4 in the study which included 83 Males and 100 females.

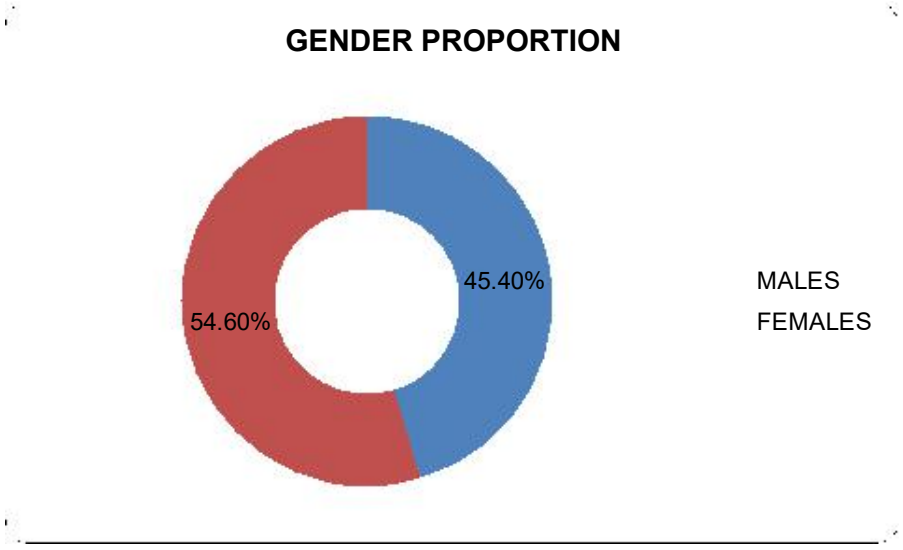



**Figure 5.2 Gender Proportion**

## CHRONIC FISSURE IN ANO

All the patients in the study presented with the classical symptoms of Chronic Fissure in ano i.e. bleeding per anum and Painful defecation

Chronic Anal fissure were further classified according to their site of location into

- ANTERIOR (7%)
- POSTERIOR (Most Common 91.25%)
- ANTERIOR + POSTERIOR (1.64%)

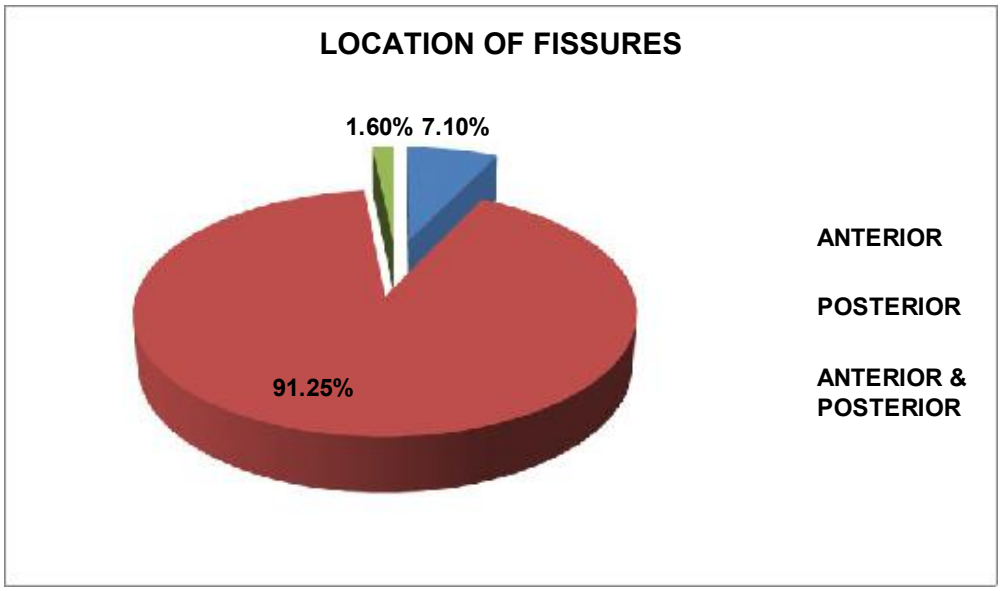



**Figure 5.3 Locations Of Chronic Anal Fissures.**

## ANALYSIS OF GROUP A - (Chemical Sphincterotomy)

In group A, total of 90 patients were treated with the Topical application of 2% Diltiazem ointment thrice daily for 6 consecutive weeks.

## FISSURE HEALING

Fissures started healing completely only by the 4th week and the final cure rate was 84.4 %( 76/90) at the 10th week.

| FISSURE HEALING RATE | | | | | |
|---|---|---|---|---|---|
| 2nd Wk | 4th Wk | 6th Wk | 8th Wk | 10th Wk | Final Cure Rate |
| 0 | 38 (42.2%) | 70 (77.78%) | 76 (84.4%) | 76 (84.4%) | 76 (84.4%) |

**Table 5.1 Fissure Healing Rate in Chemical sphincterotomy.**

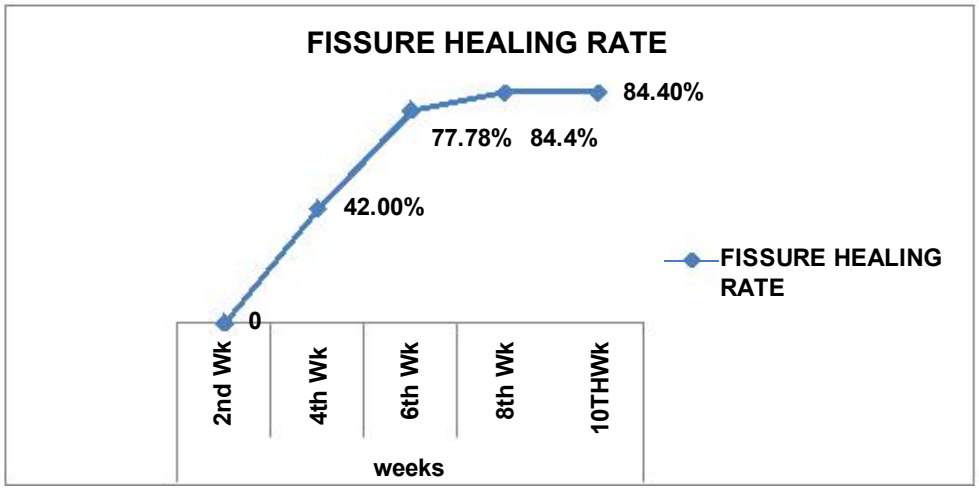



**Figure 5.4 Fissure Healing Rate In Chemical Sphincterotomy.**

## AVERAGE RECOVERY TIME

The average time taken for complete healing of Fissure was about 5.18 Weeks in Group A.

## PAIN RELIEF

The average initial pain score was 7.66 in Group A and the response to treatment in the form of immediate pain relief was achieved early in the treatment, right from the 2nd week itself. A drop in pain score from 7.66 to 3.93 occurred in first 2 weeks of treatment that is the pain was nearly halved in first 2 weeks, allowing the patients to resume their work sooner. Pain score of 3 and below (Mild) was considered to be target and was achieved by 6th week.

| INITIAL | 2nd week | 4th week | 6th week | 8th week | 10th week |
|---|---|---|---|---|---|
| 7.66 | 3.93 | 3.41 | 2.81 | 2.36 | 2.24 |

**Table 5.2 Average Pain Score In Group A**

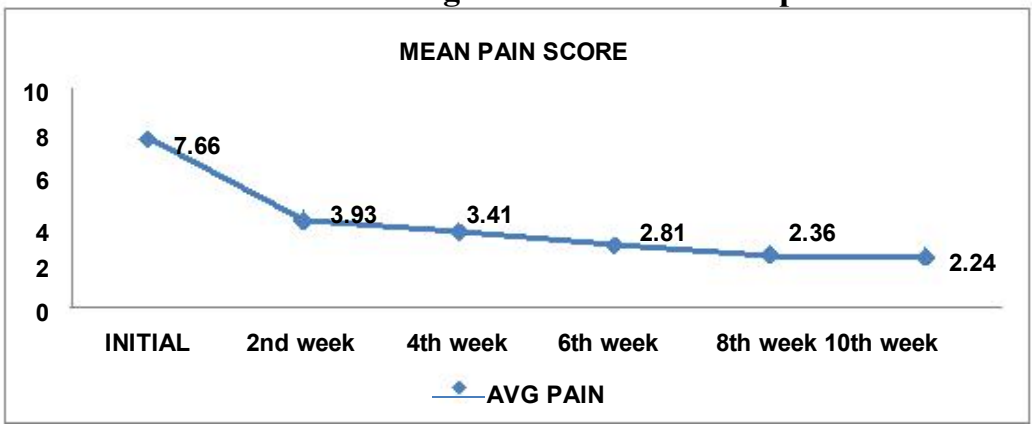



**Figure 5.5 Mean Pain Score In Group A**

## RECOVERY OF BLEEDING PER ANUM

The most apprehensive symptom of the patients, Bleeding per Anum was cured more faster than the Pain Relief. About 75% of patients were freed of this distressing symptom in first 2 weeks and by 10th week, 87.78% of patients were cured of this symptom.

| BLEEDING PR RECOVERY | | | | |
|---|---|---|---|---|
| 2nd Wk | 4thWk | 6thWk | 8thWk | 10thWk |
| 67 (74.4%) | 79 (87.78%) | 79 (87.78%) | 79 (87.78%) | 79 (87.78%) |

**Table 5.3 Recovery Of Bleeding Per Rectum**

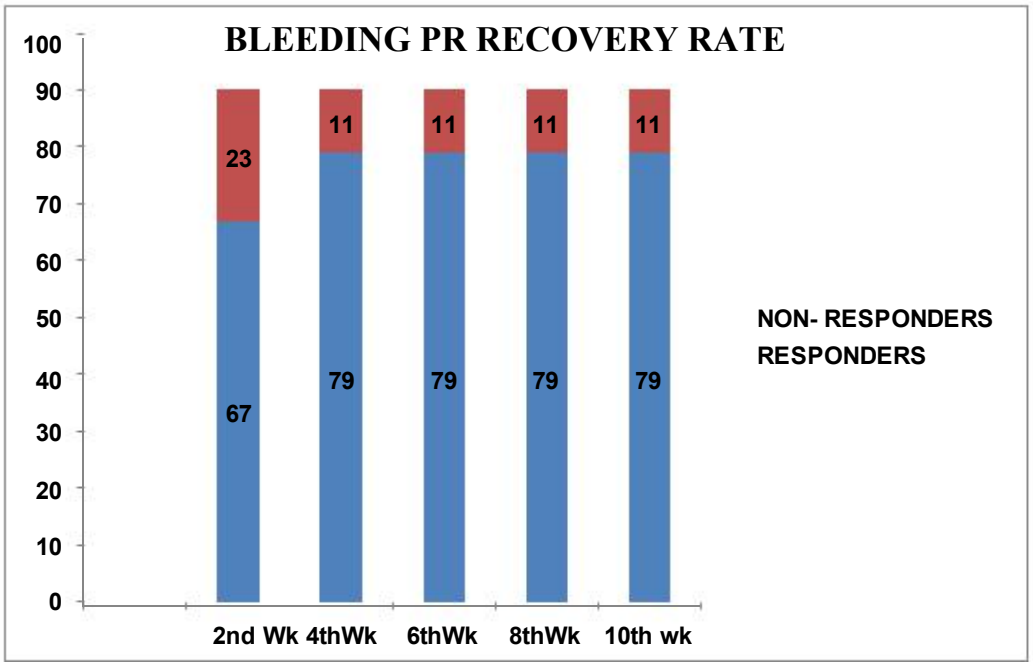



**Figure 5.6 Bleeding Per Anum Recovery Rate**

## WORK RESUME TIME

Work resume time correlated directly with the relief of Pain and Bleeding per anum symptoms which was about 3.37Weeks in Group A. In other words patients in group A resumed their day to day productive life in 3.37 weeks on an average.

## MORBIDITY OF TREATMENT

Among the Group A involving the chemical Sphincterotomy using 2% Topical Diltiazem, the major adverse effects were Headache & Itching. The incidence of itching and headache was 15.6% and 6.7% respectively. Anal Incontinence was reported to be very low i.e. only 2 out of 90 patients (2.22%) which was temporarily.

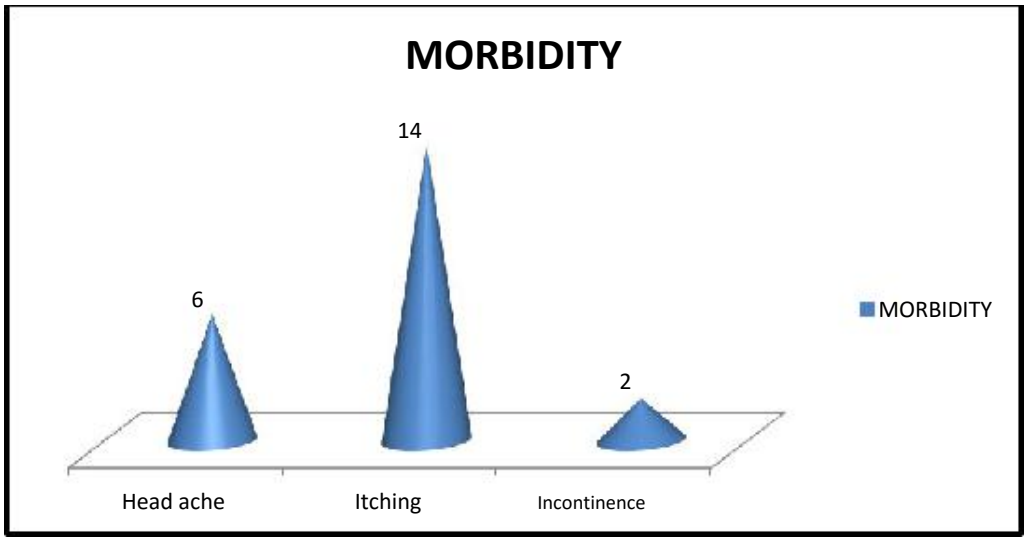



**Figure 5.7 Morbidity Of Chemical Sphincterotmy**

## RECURRENCE & CONVERSION RATE

The Recurrence rate in group A was 6.67% that is 6 patients developed Fissures at the same site after complete healing of the Fissure within 2 months past the treatment.

Similarly patients who didn't respond to chemical methods and those who had recurrences were allowed to undergo the standard surgical Sphincterotmy. They were 15 patients in this category leading to the conversion rate of 16.67%.

| RECURRENCE RATE | CONVERSION RATE |
|---|---|
| 6(6.67%) | 15(16.67%) |

**Table 5.4 Recurrence & Conversion Rate**

## ANALYSIS OF GROUP B

## (SURGICAL SPHINCTEROTOMY)

Group B patients were admitted as inpatient and treated with the standard Surgical method of Lateral Internal Sphincterotomy under spinal anaesthesia. There were 93 patients in this group after excluding the dropouts.

## FISSURE HEALING

Healing rates with the Gold Standard Surgical method was about 97.85%. Healing started by 4th week and completed by 8weeks.

| FISSURE HEALING RATE-GROUP B | | | | |
|---|---|---|---|---|
| **2nd Wk** | **4th Wk** | **6th Wk** | **8th Wk** | **10th Wk** |
| 0 | 54 (58.06%) | 88 (94.62%) | 91 (97.85%) | 91 (97.85%) |

**Table 5.5 Fissure Healing Rate In Group B**

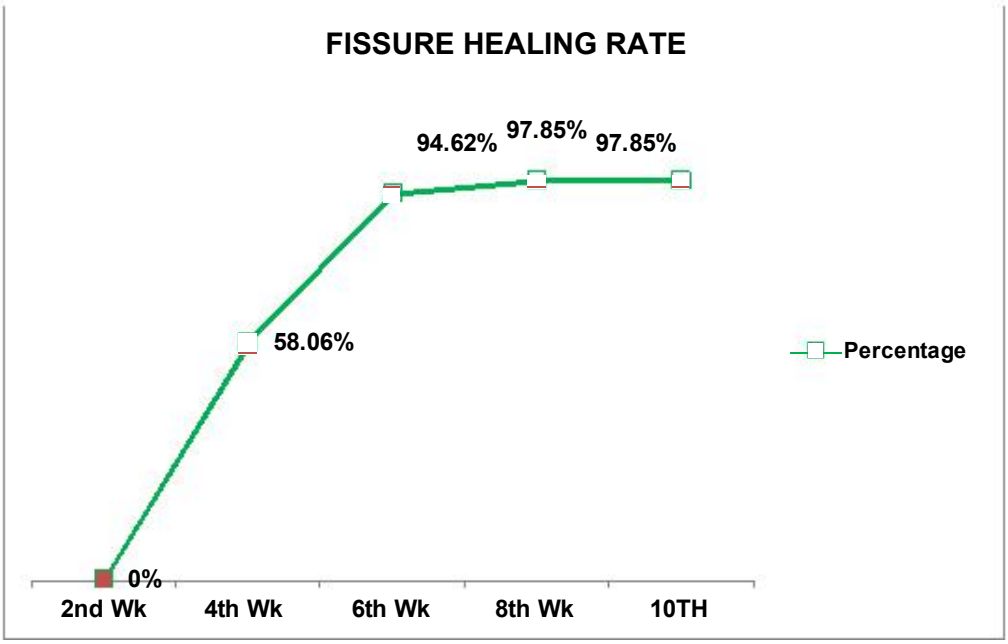



**Figure 5.8 Fissure Healing Rates In Group B**

## AVERAGE RECOVERY TIME

The average recovery time in Group B was 4.84 weeks by which the complete healing of Fissure was achieved.

## PAIN RELIEF

Pain relief was evident starting from the 2nd week and the score less than 3 was achieved by 4th week itself. The final average Pain score was 0.55 indicating complete pain relief in the patients.

| AVERAGE PAIN SCORE | | | | | |
|---|---|---|---|---|---|
| **Initial** | **2nd week** | **4th week** | **6th week** | **8th week** | **10th week** |
| 7.92 | 3.4 | 2.17 | 1.41 | 0.83 | 0.55 |

**Table 5.6 Mean Pain Score In Group B**

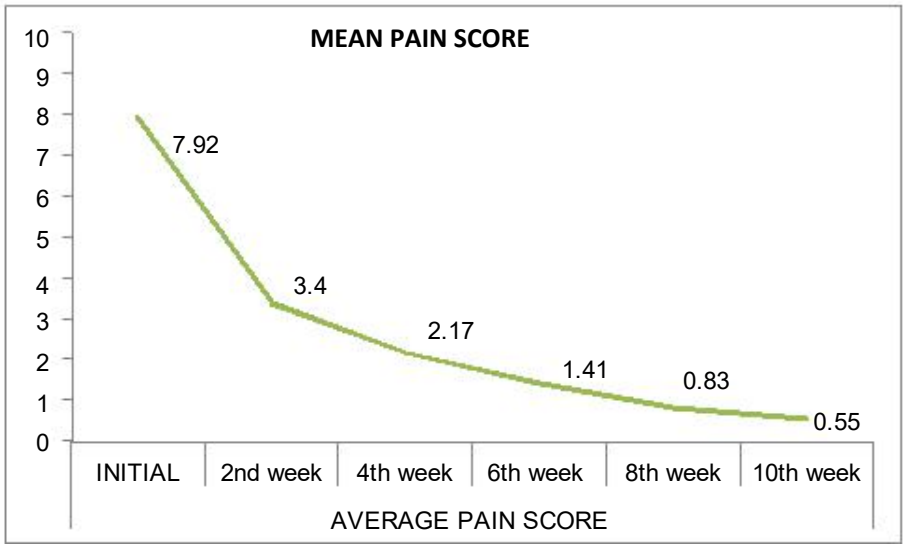



**Figure 5.9 Pain Relief Rate In Group B**

## RECOVERY OF BLEEDING PER ANUM

Bleeding per anum was relieved in 68% of patients by second week and by 10th week, 98.92% of patients had no bleeding per anum.

| BLEEDING PR RECOVERY | | | | |
|---|---|---|---|---|
| **2nd Wk** | **4thWk** | **6thWk** | **8thWk** | **10thWk** |
| 63 (67.74%) | 89 (95.7%) | 92 (98.92%) | 92 (98.92%) | 92 (98.92%) |

**Table 5.7 Recovery Of Bleeding Per Anum In Group B**

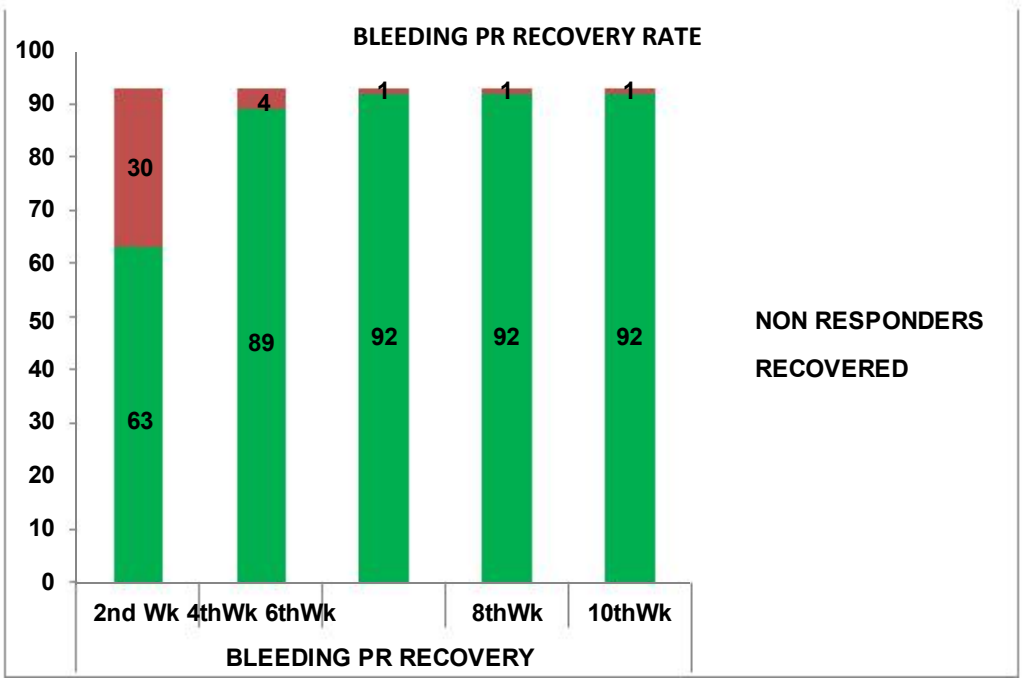



**Figure 5.10 Recovery Of Bleeding Per Anum In Group B**

## WORK RESUME TIME

Patients resumed their normal work by 3.19 weeks on an average in Group B after undergoing the Surgical sphincterotomy.

## MORBIDITY OF TREATMENT

Immediate post-surgical complications included Post-operative Pain, Bleeding from Sphincterotomy site, surgical site Infection and Faecal Incontinence.

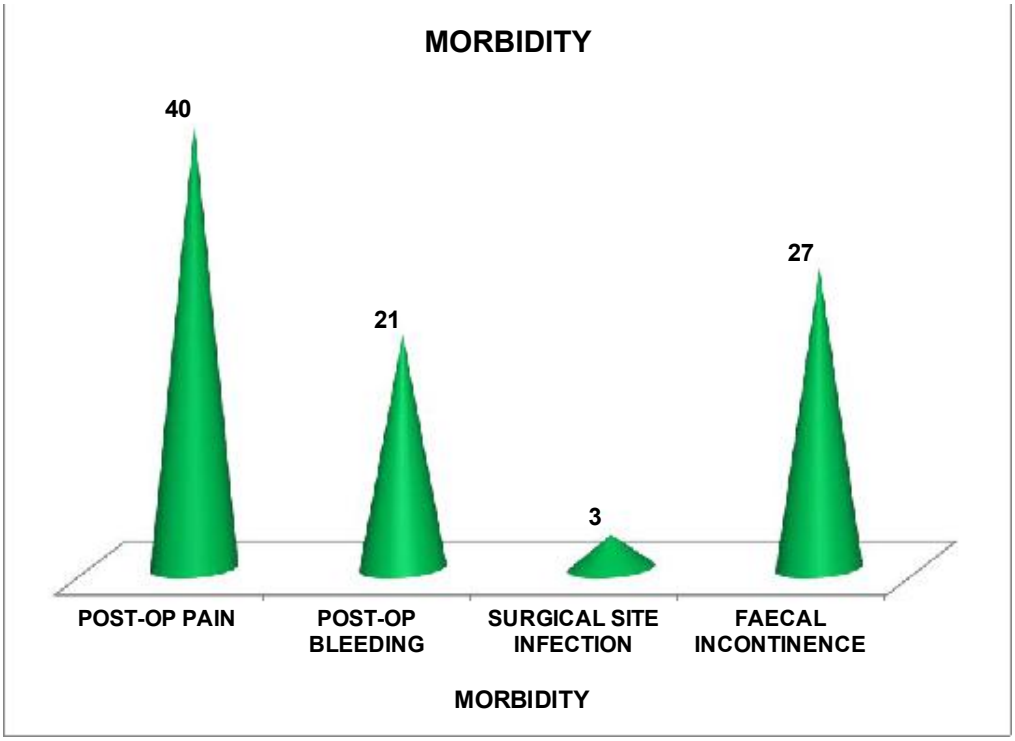



**Figure 5.11 Morbidity Of Surgical Sphincterotomy In Group B**

| MORBIDITY | PATIENTS | PERCENTAGE |
|---|---|---|
| Post-OP pain | 40 | 43.01% |
| Post-OP bleeding | 21 | 22.58% |
| Surgical Site Infection | 3 | 3.23% |
| Faecal Incontinence | 27 | 29.03% |

**Table 5.8 Morbidity Of Surgical Sphincterotomy**

Faecal Incontinence was the most distressful problem in the post- surgical patients, which was temporary in 88.89% cases, that is among the affected 27 patients, 24 had recovered from the problem in 10 weeks and 3 patients had permanent Faecal incontinence.

**RECURRENCE AND CONVERSION RATE**

In Group B involving the Surgical sphincterotomy method there was nil recurrence and the conversion rate was 2.15% (2 out of 93), proving the reliability of this Gold Standard method.

| RECURRENCE RATE | CONVERSION RATE |
|---|---|
| 0 | 2(2.15%) |

**Table 5.9 Recurrences And Conversion In Group B**

## STATISTICAL COMPARISON OF BOTH GROUP A & B

Statistical analysis

In the above study, the statistical methods were, for quantitative data, descriptive statistics was presented by N, Mean, Standard Deviation and Range. For qualitative data, frequency count N and percentage were displayed in a tabular manner.

To analyze the data, an appropriate statistical tests were applied such as to compare the two groups Independent Samples Test- t test for Equality of Means by using statistical software SPSS (version 16.0) and Other data displayed by various tables and charts by using Microsoft excel (windows 2010).

*Significant at $p < 0.05$

** very significant $p < 0.01$

*** highly significant $p < 0.001$,*** highly significant $p < 0.000$

| Independent Samples Test | | | | | | | |
|---|---|---|---|---|---|---|---|
| | t-test for Equality of Means | | | | | 95% C I of the Difference | |
| PARAMETERS | Mean Difference | t | df | p value | Std. Error Difference | Lower | Upper |
| INITIAL PAIN | -0.18 | -1.441 | 181 | 0.151 | 0.125 | -0.427 | 0.067 |
| PAIN SCORE 2ndweek | 0.546 | 2.42 | 181 | 0.016* | 0.226 | 0.101 | 0.992 |
| PAIN SCORE 4thweek | 1.239 | 5.494 | 181 | 0.0001*** | 0.226 | 0.794 | 1.684 |
| PAIN SCORE 6thweek | 1.413 | 5.694 | 181 | 0.0001*** | 0.248 | 0.923 | 1.903 |
| PAIN SCORE 8thweek | 1.528 | 6.44 | 181 | 0.0001*** | 0.237 | 1.06 | 1.996 |
| PAIN SCORE 10thweek | 1.739 | 7.12 | 181 | 0.0001*** | 0.244 | 1.257 | 2.221 |
| BPR2ndWk | -0.067 | -0.997 | 181 | 0.32 | 0.067 | -0.2 | 0.066 |
| BPR4thWk | 0.079 | 1.963 | 181 | 0.051* | 0.04 | 0 | 0.159 |
| BPR6thWk | 0.134 | 3.03 | 181 | 0.003** | 0.044 | 0.047 | 0.221 |
| BPR8thWk | 0.123 | 3.048 | 181 | 0.003** | 0.04 | 0.043 | 0.202 |
| BPR10thWk | 0.123 | 3.048 | 181 | 0.003** | 0.04 | 0.043 | 0.202 |
| FH4thWk | -0.158 | -2.158 | 181 | 0.032* | 0.073 | -0.303 | -0.014 |
| FH6thWk | -0.168 | -3.403 | 181 | 0.001** | 0.05 | -0.266 | -0.071 |
| FH8thWk | -0.134 | -3.286 | 181 | 0.001** | 0.041 | -0.215 | -0.054 |
| FINAL CURE RATE | -0.123 | -3.093 | 181 | 0.002** | 0.04 | -0.201 | -0.045 |
| INCONTINENCE | -0.268 | -5.308 | 181 | 0.0001*** | 0.051 | -0.368 | -0.168 |
| INC -TEMP | -0.236 | -4.827 | 181 | 0.0001*** | 0.049 | -0.332 | -0.139 |
| INC-PERMANENT | -0.033 | -1.732 | 180 | 0.085 | 0.019 | -0.07 | 0.005 |
| Work Resume time | 0.182 | 0.749 | 165 | 0.455 | 0.242 | -0.297 | 0.66 |
| RECOVERYTIME | 0.391 | 2.06 | 166 | 0.041* | 0.19 | 0.016 | 0.765 |
| RECURRENCE | 0.056 | 1.982 | 181 | 0.049* | 0.028 | 0 | 0.112 |
| CONVERSION | 0.16 | 3.896 | 178 | 0.0001*** | 0.041 | 0.079 | 0.24 |

**Table 5.10 Statistical Analysis of the Study**

**{ Df- degree of freedom.BPR- Bleeding per rectum, FH- Fissure healing, INC- Incontinence.}**

## FISSURE HEALING RATES OF GROUP A & B

The overall healing rates were better in Group B with 97.85% of cure rates when compared to the Group A (84.4%). Also response was quicker in Group B starting from 4th week.

| FISSURE HEALING RATE | | | | | | |
|---|---|---|---|---|---|---|
| **Group** | **2nd wk** | **4th wk** | **6th wk** | **8th wk** | **10th wk** | **Success Rate** |
| A | 0 | 38 (42.2%) | 70 (77.78%) | 76 (84.4%) | 76 (84.4%) | 76(84.4%) |
| B | 0 | 54 (58.06%) | 88 (94.62%) | 91 (97.85%) | 91 (97.85%) | 91 (97.85%) |

**Table 5.11 Comparison Of Fissure Healing Rates In Group A& B**

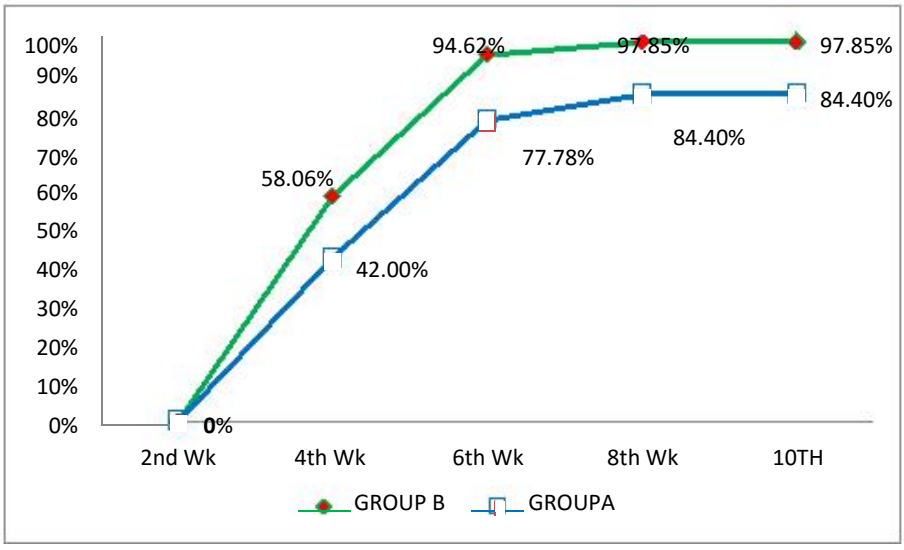



**Figure 5.12 Comparison Of Healing Rates In Group A & B**

59 The p value was found to be significant right from the 4th week (0.032*) and the final cure rate was statistically very significant with a p value of 0.002**. Thus Group B patients undergoing Surgical sphincterotomy had a better cure rate than the Group A patients with Chemical Sphincterotomy.

| Independent Samples Test | | | | | | | |
|---|---|---|---|---|---|---|---|
| | t-test for Equality of Means | | | | | 95% C I of the Difference | |
| **Fissure Healing over Weeks** | **Mean Difference** | **t** | **df** | **p value** | **Std. Error Difference** | **Lower** | **Upper** |
| 4thWeek | -0.158 | -2.158 | 181 | 0.032* | 0.073 | -0.303 | -0.014 |
| 6thWeek | -0.168 | -3.403 | 181 | 0.001** | 0.05 | -0.266 | -0.071 |
| 8thWeek | -0.134 | -3.286 | 181 | 0.001** | 0.041 | -0.215 | -0.054 |
| Final Cure Rate 10th week | -0.123 | -3.093 | 181 | 0.002** | 0.04 | -0.201 | -0.045 |

**Table 5.12 Fissure Healing Rates- p Values**

## AVERAGE RECOVERY TIME

The average recovery time was earlier in Group B (4.84Weeks) than in Group A (5.18Weeks). The p value 0.041* was statistically significant.

| Independent Samples Test | | | | | | | |
|---|---|---|---|---|---|---|---|
| | t-test for Equality of Means | | | | | 95% C I of the Difference | |
| | Mean Difference | T | df | p value | Std. Error Difference | Lower | Upper |
| RECOVERY TIME | 0.391 | 2.06 | 166 | 0.041 | 0.19 | 0.016 | 0.765 |

**Table 5.13 Recovery Time Comparison**

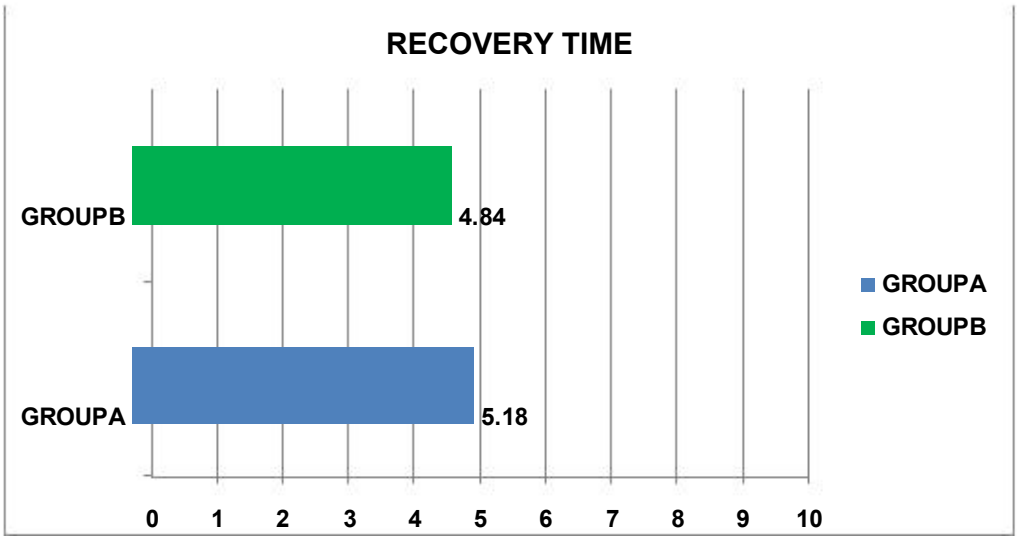



**Figure 5.13 Comparison Of Average Recovery Time**

## PAIN RELIEF

On comparison the Pain relief was much better and faster in Group B compared to Group A. Pain score less than 3 was achieved in Group B by 4th week, whereas it was only in the 6th week with Group A. The final pain scores were 0.55 in Group B and 2.24 in Group A, indicating that ultimate pain relief was better in Group B.

| PAIN SCORE MEAN | | | | | | |
|---|---|---|---|---|---|---|
| **Group** | **Initial** | **2nd week** | **4th week** | **6th week** | **8th week** | **10th week** |
| A | 7.66 | 3.93 | 3.41 | 2.81 | 2.36 | 2.24 |
| B | 7.92 | 3.4 | 2.17 | 1.41 | 0.83 | 0.55 |

**Table 5.14 Mean Pain Score In Group A & B**

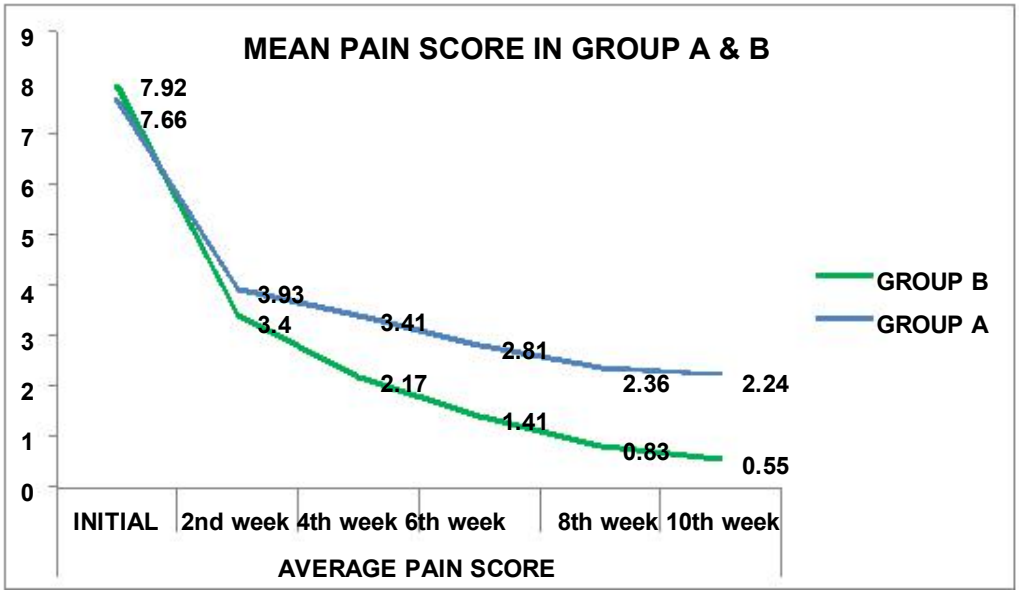



**Figure 5.14 Comparisons Of Pain Scores In Group A And B**

62 From Statistical point of view the Pain relief was significant from the 2nd week itself (p=0.016*) and then onwards it was very much

significant (p=0.0001***), clearly depicting that the Pain Relief in Group B was certainly better than Group A.

| Independent Samples Test | | | | | | | |
|---|---|---|---|---|---|---|---|
| | t-test for Equality of Means | | | | | 95% Confidence Interval | |
| **Pain Score** | **Mean Difference** | **t** | **df** | **p value** | **Std. Error Difference** | **Lower** | **Upper** |
| Initial Pain | -0.18 | -1.441 | 181 | 0.151 | 0.125 | -0.427 | 0.067 |
| 2ndweek | 0.546 | 2.42 | 181 | 0.016* | 0.226 | 0.101 | 0.992 |
| 4thweek | 1.239 | 5.494 | 181 | 0.0001*** | 0.226 | 0.794 | 1.684 |
| 6thweek | 1.413 | 5.694 | 181 | 0.0001*** | 0.248 | 0.923 | 1.903 |
| 8thweek | 1.528 | 6.44 | 181 | 0.0001*** | 0.237 | 1.06 | 1.996 |

**Table 5.15 Statistical p Value For Pain Relief**

**RECOVERY OF BLEEDING PER ANUM**

Bleeding per anum became nil for 87.78% of patients in Group A and 98.92% of patients in Group B by the end of 10th week, which correlated with the Fissure healing rates. Recovery was actually better in Group B but appeared to be little faster in Group A during the early course of treatment i.e. first 2 weeks.

| | BLEEDING PR RECOVERY | | | | |
|---|---|---|---|---|---|
| **Group** | **2nd Wk** | **4thWk** | **6thWk** | **8thWk** | **10thWk** |
| A | 67 (74.4%) | 79 (87.78%) | 79 (87.78%) | 79 (87.78%) | 79 (87.78%) |
| B | 63 (67.74%) | 89 (95.7%) | 92 (98.92%) | 92 (98.92%) | 92 (98.92%) |

**Table 5.16 Comparison Of Recovery Of Bleeding Per Anum**

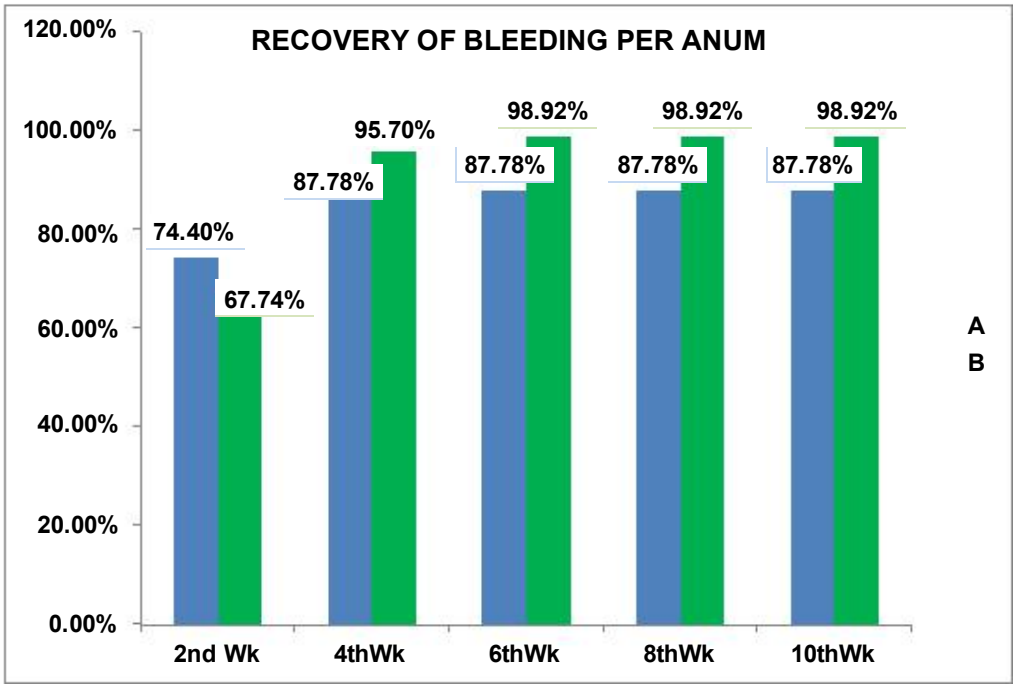



**Figure 5.15 Comparison Of Recovery Of Bleeding Per Anum In Group A & B**

The recovery of Bleeding per anum was statistically significant from the 4$^{th}$ week onwards with p value of 0.051*. In the subsequent weeks (6$^{th}$ , 8$^{th}$ & 10$^{th}$ week) the p value was very significant (p=0.003**), showing that the recovery was better in Group B.

| Independent Samples Test | | | | | | | |
|---|---|---|---|---|---|---|---|
| | t-test for Equality of Means | | | | | 95% Confidence Interval | |
| Pain Score | Mean Difference | t | df | p value | Std. Error Difference | Lower | Upper |
| 2ndWk | -0.067 | -0.997 | 181 | 0.32 | 0.067 | -0.2 | 0.066 |
| 4thWk | 0.079 | 1.963 | 181 | 0.051* | 0.04 | 0 | 0.159 |
| 6thWk | 0.134 | 3.03 | 181 | 0.003** | 0.044 | 0.047 | 0.221 |
| 8thWk | 0.123 | 3.048 | 181 | 0.003** | 0.04 | 0.043 | 0.202 |
| 10thWk | 0.123 | 3.048 | 181 | 0.003** | 0.04 | 0.043 | 0.202 |

**Table 5.17 Comparison Of Recovery Of Bleeding Per Anum In Group A & B**

## WORK RESUME TIME

Work resuming Time was little better with Group B (3.19Weeks) over Group A(3.37Weeks) with p value of 0.455, suggesting not much of statistical significance.

## MORBIDITY OF TREATMENT

Each group had its own specific morbid aspects such as Headache & Itching in Group A and Post-operative pain, Surgical site bleeding & Infection in Group B, which could not be compared.

65 Faecal incontinence was the factor specially measured in both groups. Group A patients had better continence profile than the Group B

(Surgical).

| FAECAL INCONTINENCE | | | |
|---|---|---|---|
| **GROUP** | **+/-** | **TEMP** | **PERMANENT** |
| A | 2(2.22%) | 2 | 0 |
| B | 27(29.03%) | 24(25.80%) | 3(3.22%) |

**Table 5.18 Comparison Of Faecal Incontinence**

And that p value was very much significant (0.0001***), suggesting that the incidence of Faecal incontinence in Group A was very rare, while it was common with (Group B ) Post-surgical patients.

| Independent Samples Test | | | | | | | |
|---|---|---|---|---|---|---|---|
| | t-test for Equality of Means | | | | | 95% Confidence Interval | |
| | **Mean Difference** | **t** | **df** | **p value** | **Std. Error Difference** | **Lower** | **Upper** |
| Incontinence | -0.268 | -5.308 | 181 | 0.0001*** | 0.051 | -0.368 | -0.168 |

**Table 5.19 Faecal Incontinence Comparison p Value.**

## RECURRENCE AND CONVERSION RATE

Recurrence with the Surgical method was nil and its conversion rate due to failure was only 2.15% (2/93). Whereas in Group A , the Recurrence was 6 out of 90(6.67%) and the conversion rate was 16.67% (15 out of 90, including both failures and recurrence cases). The statistical analysis showed that the Recurrence in Group A was significant (p=0.049*) and the conversion rate was very much significant (p=0.0001***).

| Independent Samples Test | | | | | | | |
|---|---|---|---|---|---|---|---|
| | t-test for Equality of Means | | | | | 95% Confidence Interval | |
| | Mean Difference | t | D f | p value | Std. Error | Lower limit | Upper limit |
| Recurrence rate | 0.056 | 1.982 | 181 | 0.049* | 0.028 | 0 | 0.112 |
| Conversion rate | 0.16 | 3.896 | 178 | 0.0001*** | 0.041 | 0.079 | 0.24 |

**Table 5.20 Statistical p Values Of Recurrence & Conversion Rates.**

# DISCUSSION

The analysis of the study between both the treatment groups was done and the results were compared with literature for establishing its significance. Starting from the primary objective of Fissure healing rates to the secondary objectives of recovery of Pain, Bleeding Per anum, Morbidity of the treatment & Recurrence rate were analysed and discussed in a detailed manner.

## Fissure Healing Rate[71-76]

In the present study the overall healing rates were better in Group B with 97.85% of cure rates when compared to that of the Group A(84.4%). Healing of fissure was completed by 4 to 8 weeks in both the groups. But response was quicker in Group B starting from 4$^{th}$ week.

When compared with the previous similar studies in the literature the healing rate of chemical method with 2% Topical Diltiazem were ranging from 60 to 89%. The Fissure healing rate in the present study is comparable with most of the studies.

| Study | Healing rate with Diltiazem 2% |
|---|---|
| Rithin Suvarna Et al 2012 | 69.23% |
| Giridhar C. M Et al 2014 | 88.4% |
| Ansar Latif Et al 2013 | 74% |
| Manjunath S Kotennava Et al 2012 | 60% |
| Rajan vaithyanathan Et al 2015 | 71% |
| Madhusudhan M. Et 2014 | 89.36% |
| Nelson et al. 2012 | 80% |
| Sanei et al. 2009 | 67% |
| **Present study** | **84.4%** |

**Table 6.1 Healing Rates with 2 % Diltiazem in Chronic Fissure in Ano.**

The healing rates with Surgical method was constantly high(>95%) in all the above trials including the present study.

**Recovery time [71-76]**

The average Recovery time with Topical Ditiazem was 5.18 weeks which is one of the lesser recovery time as compared to literature(Table6.2) and is very close to that of the Surgical method(4.84 weeks in the present study).

| Study | Average recovery time with topical 2%diltiazem |
|---|---|
| Sanei et al. 2009 | 7.58±2.01 |
| Abd Elhady et al. 2009 | 5.1±1.13 weeks |
| Manjunath S Kotennavar et al 2012 | 7.2 weeks |
| Giridhar C. M et al 2014 | 5.04 weeks |
| **PRESENT STUDY** | **5.18 weeks** |

**Table 6.2 Average Recovery Time with 2% Topical Diltiazem**

**Pain Recovery[71-76]**

On comparison the Pain relief was much better and faster in Group B compared to Group A. Pain score less than 3 was achieved in Group B by 4th week, and in group A by 6th week. The final pain scores were 0.55 in Group B and 2.24 in Group A, indicating that ultimate pain relief was better in Group B. The total percentage of pain recovery was 84% in Group A, which is comparable with the literature(Table6.3).

| Study | Final Pain Score | % Of Recovery With Diltiazem |
|---|---|---|
| Madhusudhan M. et al 2014 | - | 89.4% |
| Rajavaithyanathan et al 2015 | 3.38 | - |
| Giridhar C. M et al 2014 | - | 78.26% |
| **PRESENT STUDY** | **2.24** | **84%** |

**Table 6.3 Pain Recovery with 2 % Diltiazem**

**Recovery of Bleeding per Anum**

The total recovery rate by the 10th week in group A was 87.78% and that of Group B was 98.92%. Not much of the studies give data regarding the recovery of bleeding per anum. But the available literature suggests that the recovery of bleeding per anum is one of the earliest response to the treatment along with the Pain recovery (Table6.4). In our study the response was quicker in both groups. The cure of bleeding per anum was achieved by 2weeks in nearly 75% patients of both Groups, which is faster as comparedto that achieved by Manjunath S Koteennavaret al.

| Study | Early response time |
|---|---|
| Manjunath S Kotennavar et al 2012 | 3weeks |
| **Present Study** | **2 weeks** |

**Table 6.4 Recovery of Bleeding per rectum with diltiazem.**

## MORBIDITY OF THE TREATMENT[71-76]

### I. Faecal Incontinence rate

Faecal incontinence was analysed based on the duration and separately classified as Temporary (<10 weeks) and Permanent (>10weeks).

The Temporary incontinence was initially reported to be in 2.22% patients of Group A and 29.03% patients in Group B. The permanent incontinence was nil in Group A and was about in 3.22% in Group B which correlates with the data available in the literature (Table6.5).

| STUDY | 2% Diltiazem | Surgical Sphincterotomy |
|---|---|---|
| Madhusudhan M. et al 2014 | Nil | 2.1% |
| Ansar Latif et al 2013 | Nil | 6% |
| Rithin Suvarna et al 2012 | Nil | 9.27% |
| Majid Aziz et al 2009 | Nil | 3.33% |
| **Present Study** | **Temporary- 2.22%**<br>**Permanent- Nil** | **Temporary-29.03%**<br>**Permanent- 3.22%** |

**Table 6.5 Faecal Incontinence Rate in Surgical and Diltiazem Groups**

## II. Headache

The headache was specifically associated with Group A and its incidence was much lower 6.7% than with that of Glyceryl trinitrate (67%) as reported by Rithin Suvarna et al.

| STUDY | Incidence of Headache |
|---|---|
| Manjunath S Kotennavar et al 2012 | 5.71% |
| Rithin Suvarna et al 2012 | 5.49% |
| **Present Study** | **6.7%** |

**Table 6.6 Headache in Diltiazem group**

## III. Itching

Local itching was reported to be in 15.6% patients of Group A, which was higher than that reported by madhusudhan M et al(4.3%). But it was mostly temporary which lasted few minutes after application of the Ointment.

| Study | Incidence of Itching |
|---|---|
| Madhusudhan M et al 2014 | 4.3% |
| **Present Study** | **15.6%** |

**Table 6.7 Incidence of Itching in Diltiazem group**

## IV. Post-operative Pain, Surgical Site Bleeding & Infection

In the Surgical group the specific drawbacks were Post-operative pain (43.01%), Surgical site bleeding (22.58%) & Infection (3.23%).

| Study | Infection Rate |
|---|---|
| Rajan Vaithianathan et al 2015 | 4.44% |
| **Present Study** | **3.23%** |

**Table 6.8 Infection rate in Surgical group.**

### Recurrence Rate[71-76]

In the present study the recurrence rate in Group A (2% Diltiazem) was 6.67%, whereas it was nil with surgical method. The recurrence rate in the current Study was much lower than that reported in the literature. The data suggests Chemical sphincterotomy can definitively be used as an alternative to surgery when used with proper methodology and compliance.

| Study | Recurrence rate |
|---|---|
| Nelson et al. 2012 | 12.5% |
| **Abd Elhady et al. 2009** | 65% |
| **Samim et al. 2012** | 17.6% |
| **Suvarna et al. 2012** | 10.43% |
| **Cevik et al. 2011** | 11.1% |

| Study | Recurrence rate |
|---|---|
| Madhusudhan M et al 2014 | 2.1% |
| Ansar Latif et al 2013 | 25% |
| Rithin Suvarna et al 2012 | 10.43% |
| **Present Study** | **6.67%** |

**Table 6.9 Recurrence Rate in Diltiazem Groups**

The final inference drawn from these observations is that the Chemical Sphincterotomy using 2% Diltiazem has better side effect profile and good comparable healing rates in the treatment of Chronic Anal Fissures. The drawbacks that could be mentioned are the slower response, longer duration of treatment and more chances of recurrence. Considering all these parameters it could be recommended that 2% Topical Diltiazem is the best available alternative for Surgical method in treatment of chronic fissure in ano.. And surgery can be reserved for Non-responders alone.

# SUMMARY

The current study was an interventional study which compared the Chemical Sphincterotomy (using 2% Topical Diltiazem gel) with Surgical Sphincterotomy (Open Lateral Internal Sphincterotomy). The sample was selected from the population with specific Inclusion & Exclusion criteria. The total sample size was 189 of which 6 were dropouts. So only 183 patients were studied in this trial of which 90 belonged to Group A (Chemical Sphincterotomy) and 93 belonged to Group B (Surgical Sphincterotomy). The following parameters were compared between the two groups.

- Fissure Healing Rate
- Pain Recovery Rate
- Bleeding per Anum Recovery Rate
- Work Resume Time
- Morbidity of the Treatment
- Faecal incontinence
- Recovery Time
- Recurrence Rate
- Conversion Rate

77 The study was done in ESIC Medical College & PGIMSR Chennai-78 between November2013 to May 2015. The findings were interpreted as below

**Fissure Healing Rate:**

The final cure rate at 10th week for both the Groups was 84.4% in Chemical sphincterotomy and 97.85% in surgical sphincterotomy. The complete Fissure healing was documented from 4th week in both the Groups. The Surgical sphincterotomy had better healing than the Chemical method which was also statistically very significant.

**Pain Recovery Rate**:

The pain recovery was evident from the 2nd week in both the groups with the initial pain being halved. The final average pain score by 10th week in Group A (chemical Sphincterotomy) was 2.24, which was acceptable. Whereas in Group B (Surgical sphincterotomy) the final pain average was 0.55 (very negligible) showing complete resolution of symptoms. The rate of recovery was also faster in Group B than Group A.

**Bleeding Per Anum Recovery Rate:**

The recovery of Bleeding per anum also occurred early in the treatment by 2nd week in both the groups. The final recovery rates by 10th week were 87.78% in Group A and 98.92% in Group B, which correlates with Fissure healing rates.

**Work Resume Time:**

The average work resuming time were 3.37 weeks in Group A (Chemical Sphincterotomy) and 3.19 weeks in Group B which correlated with the recovery of Pain and Bleeding per anum. The work resuming time was not statistically significant.

**Recovery Time**:

The recovery time showed the average Fissure Healing time. It was better in group B ( Surgical Sphincterotomy) with about 4.84 weeks as its average recovery time while it was 5.18 weeks with Group A(Chemical sphincterotomy).

**Morbidity of Treatment**

Each group had its unique drawbacks. Group A had headache (6.7%) and itching (15.6%) as its unique side effects. Group B patients had Post-operative Pain (43.01%), Surgical site bleeding (22.58%) and Surgical site infections (3.23%).

**Faecal incontinence**

Faecal incontinence was mostly experienced by the Group B (Surgical sphincterotomy) patients in about 29.03% of them. Whereas it was only 2.22% in Group A Patients (Chemical Sphincterotomy), that too only temporarily. Also out of the 27 patients only 3 had permanent incontinence.

**Recurrence Rate & Conversion Rate**

There was nil recurrence in Surgical limb (Group B) re-establishing that it is the Gold Standard in the treatment of Chronic fissure in ano. In group A (chemical Limb) the recurrence rate was 6.67%.

The conversion rate was about 16.67% in Group A and 2.15% in group B reflecting that failure rates were higher in Group A so that patients needed to shift to the Gold standard treatment.

The final inference from the study was that Group B (Surgical sphincterotomy) patients definitely had better recovery & response to the treatment than the Group A (Chemical Sphincterotomy) patients. The only notable major drawback was the higher faecal incontinence

rate in Group B. On the other hand group A patients also had significantly good recovery and response to the Chemical sphincterotomy method with lesser morbidity.

# CONCLUSION

In present study it was observed that Chemical sphincterotomy with 2% Topical Diltiazem in the management of Chronic fissure in ano in comparison with surgical sphincterotomy has : -

I) Significant fissure healing rate

II) Early recovery of bleeding per anum and pain with lesser recovery time

III) Least side effect profile including risk of faecal incontinence

IV) Significant recurrence rate requiring surgical modality for non-responders.

V) Needs proper patient education, motivation and compliance

Thus the present study concludes that the Chemical sphincterotomy with 2% Topical Diltiazem gel should be used as the primary treatment of choice in the management of Chronic fissure in ano, while the surgical method must be kept reserved for the non-responders.

# BIBLIOGRAPHY


1. Gott, M. D.; Peter, H. (5 March 1998). "New Therapy Coming for Anal Fissures". The Fresno Bee (Fresno, CA: McClatchy Co). p. E2, "Life" section.

2. Collins, E. E.; Lund, J. N. (September 2007). "A Review of Chronic Anal Fissure Management". Techniques in Coloproctology11 (3): 209–223. doi:10.1007/s10151-007-0355-9.PMID 17676270.

3. Best Practice. British Medical Journal. Apr 23, 2012. Retrieved 30 June 2012.

4. Basson, Marc D. (28 January 2010). "Constipation". eMedicine.New York, NY: WebMD. Retrieved 5 April 2010.

5. Nelson RL, Thomas K, Morgan J, Jones A (2012). "Non surgical therapy for anal fissure". Cochrane Database of Systematic Reviews2:CD003431. doi:10.1002/14651858.CD003431.pub3.PMID 22336789.

6. Haq., Z.; Rahman, M.; Chowdhury, R.; Baten, M.; Khatun, M. (2005). "Chemical Sphincterotomy—First Line of Treatment for Chronic Anal Fissure". Mymensingh Medical Journal 14 (1): 88–90.PMID 15695964.

7. Shao, WJ; Li, GC; Zhang, ZK (September 2009). "Systematic

review and meta-analysis of randomized controlled trials comparing botulinum toxin injection with lateral internal sphincterotomy for chronic anal fissure". International journal of colorectal disease 24(9): 995–1000. doi:10.1007/s00384-009-0683-5.PMID 19266207.

8. Anal Fissure – Treatment Overview". WebMD. Retrieved27 September 2011.

9. Poritz, Lisa Susan. "Anal Fissure Treatment & Management". Medscape. Retrieved 27 September 2011.

10. Loder, P.; Kamm, M.; Nicholls, R.; Phillips, R. (1994). "'Reversible Chemical Sphincterotomy' by Local Application of Glyceryl Trinitrate". British Journal of Surgery 81 (9): 1386–1389.doi:10.1002/bjs.1800810949. PMID 7953427.

11. Lockhart Mummery JP (1934) Diseases of the rectum and colon and their surgical treatment. (MacMillan, Toronto)

12. Pescatori M, Interisano A (1995) Annual report of the Italian coloproctology units. Tech Coloproctol 3:29-30

13. Klosterhalfen B, Vogel P, Rixen H, ef al. (1989) Topography of the inferior rectal artery: a possible cause of chronic,primary anal fissure. Dis Colon Rectum 32:43-52.

14. Prohm P, Bonner C (1995) Is manometry essential for surgery of chronic fissure-in-ano? Dis Colon Rectum38:735-738.

15. Schouten WR, Briel JW, Auwerda JJ (1994) Relationship between anal pressure and anodermal blood flow. The vascular

pathogenesis of anal fissures. Dis Colon Rectum 37:664- 669.

16. Minguez M, Tomas-Ridocci M, Garcia A, ef al. (1992) Pressure of the anal canal in patients with haemorrhoids or with anal fissure. Effect of the topical application of an anaesthetic gel. Rev Esp Enferm Dig 81:103-107.

17. Rosen L, Abel ME, Gordon PH, ef al. (1992) Practice parameters for the management of anal fissure. The Standards Task Force American Society of Colon and Rectal Surgeons. Dis Colon Rectum 35:206-208.

18. Notaras MJ (1969) Lateral subcutaneous sphincterotomy for anal fissure—a new technique. Proc R Soc Med 6

19. Khubchandani IT, Reed JF (1989) Sequelae of internal sphincterotomy for chronic fissure in ano. Br J Surg 76:431-434.

20. Pernikoff BJ, Eisenstat TE, Rubin RJ, ef al. (1994) Reappraisal of partial lateral internal sphincterotomy. Dis Colon Rectum 37:1291-1295.

21. Sultan AH, Kamm MA, Nicholls RJ, ef al. (1994) Prospective study of the extent of internal anal sphincter division during lateral sphincterotomy. Dis Colon Rectum 37:1031-1033.

22. Garcia-Aguilar J, Belmonte Montes C, Perez JJ, ef al. (1998) Incontinence after lateral internal sphincterotomy: anatomic and functional evaluation [see comments]. Dis Colon

Rectum 41:423-427. 23

23. Garcia-Aguilar J, Belmonte C, Wong WD, ef al. (1996) Open vs closed sphincterotomy for chronic anal fissure: long-term results. Dis Colon Rectum 39:440-443.

24. 24Jensen SL, Lund F, Nielsen OV, ef al. (1984) Lateral subcutaneous sphincterotomy versus anal dilatation in the treatment of fissure in ano in outpatients: a prospective randomised study. BMJ 289:528-530.

25. 25Abcarian H (1980) Surgical correction of chronic anal fissure: results of lateral internal sphincterotomy vs fissurectomy-midline sphincterotomy. Dis Colon Rectum 23:31-36.

26. (1980) Classic articles in colonic and rectal surgery. Stretching, massage and rhythmic percussion in the treatment of muscular contractions: Joseph-Claude-Anthelme Recamier (1774- 1852). Dis Colon Rectum 23:362-367.

27. Lord PH (1968) A new regime for the treatment of haemorrhoids. Proc R Soc Med 61:935-936. Weaver RM, Ambrose NS, Alexander-Williams J, ef al. (1987) Manual dilatation of the anus vs lateral subcutaneous sphincterotomy in the treatment of chronic fissure-in-ano. Results of a prospective, randomized, clinical trial. Dis Colon Rectum 30:420-423.

28. Sohn N, Eisenberg MM, Weinstein MA, ef al. (1992) Precise anorectal sphincter dilatation—its role in the therapy of anal fissures. Dis Colon Rectum 35:322-327.

29. Marby M, Alexander-Wlliams J, Buchmann P, ef al. (1979) A randomized controlled trial to compare anal dilatation with lateral subcutaneous sphincterotomy for anal fissure. Dis Colon Rectum 22:308-311.

30. Giebel GD, Horch R (1989) Treatment of anal fissure: a comparison of three different forms of therapy. Nippon Geka Hokan 58:126-133.

31. Saad AM, Omer A (1992) Surgical treatment of chronic fissure-in-ano: a prospective randomised study. East Air Med J 69:613-615.

32. Oliver DW, Booth MW, Kernick VF, ef al. (1998) Patient satisfaction and symptom relief after anal dilatation. Int J Colorectal Dis 13:228-231.

33. Speakman CT, Burnett SJ, Kamm MA, ef al. (1991) Sphincter injury after anal dilatation demonstrated by anal endosonography. Br J Surg 78:1429-1430.

34. Nielsen MB, Rasmussen OO, Pedersen JF, ef al. (1993) Risk of sphincter damage and anal incontinence after anal dilatation for fissure-in-ano. An endosonographic study. Dis Colon Rectum 36:677-680.

35. Collopy B, Ryan P (1979) Comparison of lateral subcutaneous sphincterotomy with anal dilatation in the treatment of fissure in ano. Med J Aust ii:461-462, , 487..

36. Rattan S, Sarkar A, Chakder S (1992) Nitric oxide pathway in

rectoanal inhibitory reflex of opossum internal anal sphincter. Gastroenterology 103:43-50

37. O'Kelly T, Brading A, Mortensen N (1993) Nerve mediated relaxation of the human internal anal sphincter: the role of nitric oxide. Gut 34:689-693.

38. Stebbing JF (1998) Nitric oxide synthase neurones and neuromuscular behaviour of the anorectum. Ann R Coll Surg Engl 80:137-145

39. Loder PB, Kamm MA, Nicholls RJ, ef al. (1994) "Reversible chemical sphincterotomy" by local application of glyceryl trinitrate. Br J Surg 81:1386-1389.

40. Guillemot F, Leroi H, Lone YC, ef al. (1993) Action of in situ nitroglycerin on upper anal canal pressure of patients with terminal constipation. A pilot study. Dis Colon Rectum 36:372-376.45. Carapeti EA, Kamm MA, McDonald PJ, ef al. (1999) Randomised controlled trial shows that glyceryl trinitrate heals anal fissures, higher doses are not more effective, and there is a high recurrence rate. Gut 44:727-730.

41. Langman’s Medical Embryology 12th edition: chapter15:pg229.

42. Majid Aziz, Faran Kiani, Shahzad Ahmed Qasmi:Journal of Surgery Pakistan (International) 17 (1) January - March 2012;

43. Medscape : Management of Anal Fissures: online contents.

44. Lysy J, Israelit-Yatzkan Y, Sestiere-lttah M, ef al. (1998)

Treatment of chronic anal fissure with isosorbide dinitrate: long-term results and dose determination. Dis Colon Rectum 41:1406-1410.

45. Hallan Rl, Wlliams NS, Melling J, ef al. (1988) Treatment of anismus in intractable constipation with botulinum A toxin. Lancef i i: 714-717.

46. Schouten WR, Briel JW, Boerma MO, ef al. (1996) Pathophysiological aspects and clinical outcome of intra-anal application of isosorbide dinitrate in patients with chronic anal fissure. Gut 39:465-469.

47. Bacher H, Mischinger HJ, Werkgartner G, ef al. (1997) Local nitroglycerin for treatment of anal fissures: an alternative to lateral sphincterotomy? Dis Colon Rectum 40:840-84

48. Watson SJ, Kamm MA, Nicholls RJ, ef al. (1996) Topical glyceryl trinitrate in the treatment of chronic anal fissure. Br J Surg 83:771-775.

49. Gunn J, Varma A, Monson J, ef al. (1998) The dose response of the internal anal sphincter to topical application of glyceryl trinitrate cream [abstract]. Dis Colon Rectum 41.

50. Dorfman G, Levitt M, Platell C (1999) Treatment of chronic anal fissure with topical glyceryl trinitrate. Dis Colon Rectum 42:1007-1010.

51. Lund JN, Scholefield JH (1997) A randomised, prospective, double-blind, placebo-controlled trial of glyceryl trinitrate

ointment in treatment of anal fissure [see comments] [published erratum appears in Lancet 1997;349:656]. Lancef

52. Lund JN, Parsons SL, Scholefield JH (1996) Spasm of the internal anal sphincter in anal fissure—cause or effect?

53. Jost WH, Schimrigk K (1993) Use of botulinum toxin in anal fissure [letter]. Dis Colon Rectum 36:974.

54. Maria G, Cassetta E, Gui D, ef al. (1998) A comparison of botulinum toxin and saline for the treatment of chronic anal fissure [see comments]. NEnglJ Med 338:217-220.

55. Jost WH, Schimrigk K (1994) Therapy of anal fissure using botulin toxin [see comments]. Dis Colon Rectum 37:1321-1324.

56. Espi A, Melo F, Minguez M, ef al. (1998) Therapeutic effects of different doses of botulinum toxin in chronic anal fissure [abstract]. Dis Colon Rectum 41:A16.

57. Jost WH (1997) One hundred cases of anal fissure treated with botulin toxin: early and long-term results [see comments]. Dis Colon Rectum 40:1029-1032

58. Jost WH, Schrank B (1999) Repeat botulin toxin injections in anal fissure: in patients with relapse and after insufficient effect of first treatment. Dig Dis Sci 44:1588-1589.

59. Mason PF, Watkins MJ, Hall HS, ef al. (1996) The management of chronic fissure in-ano with botulinum toxin [see comments]. J R Coll Surg Edinb 41:235-238.

60. Boquet J, Moore N, Lhuintre JP, ef al. (1986) Diltiazem for proctalgia fugax [letter]. Lancet i:1493.

61. Jonard P, Essamri B (1987) Diltiazem and internal anal sphincter [letter]. Lancet i:754.

62. Carapeti EA, Kamm MA, Evans BK, ef al. (1998) Diltiazem lowers resting anal sphincter pressure. A potential low side-effect alternative to glyceryl trinitrate (GTN) for fissures [abstract]. Gut 42 (suppl 1) A97.

63. Cook TA, Humphreys MM, Mortensen NJ (1999) Oral nifedipine reduces resting anal pressure and heals chronic anal fissure. BrJ Surg 86:1269-1273

64. Brisinda G, Maria G, Bentivoglio AR, ef al. (1999) A comparison of injections of botulinum toxin and topical nitroglycerin ointment for the treatment of chronic anal fissure [see comments]. N EnglJ Med 341:65-69.

65. Bhatia KP, Munchau A, Thompson PD, ef al. (1999) Generalised muscular weakness after botulinum toxin injections for dystonia: a report of three cases. J Neurol Neurosurg Psychiatry 67:90-93.

66. Latimer PR, Hodgkins PR, Vakalis AN, ef al. (1998) Necrotising fasciitis as a complication of botulinum toxin injection. Eye 12:51-53.

67. Fiacchino F, Grandi L, Soliveri P, ef al. (1997) Sensitivity to vecuronium after botulinum toxin administration. J Neurosurg Anesthesiol 9:149-153.

68. Truong DD, Cullis PA, O'Brien CF, ef al. (1997) BotB (botulinum toxin type B): evaluation of safety and tolerability in botulinum toxin type A-resistant cervical dystonia patients (preliminary study). Mov Disord 12:772-775.

69. Mezaki T, Kaji R, Brin MF, ef al. (1999) Combined use of type A and F botulinum toxins for blepharospasm: a double-blind controlled trial. Mov Disord 14:1017-1020

70. Ansar Latiff, Anila Ansar Muhammad, Pak J Med Sci.2013, 2*9(5):1230-1235.*

71. Rithin Suvarna, Panchami, Guruprasad Rai D. Chemical Sphicterotomy versus Surgical Sphicterotomy in the Management of Chronic Fissure in ANO: A Prospective, Randomized Trial. DOI: JCDR/2012/4386:0000

72. JP Garner, M McFall, DP Edwards group.bmj.com J R Army Med Corps 2002; 148: 230-235

73. Rithin Suvarna, Hanumanthappa MB * , Panchami , Guruprasad Rai, Int J Biol Med Res. 2012; 3(2): 1747-1750

74. Madhusudhanan et al JEMDS2014:june:vol 3:issue 22:6243-6251

75. 1Dr. Manjunath S Kotennavar*, 1Dr. Arvind K Patil, 1Dr. Amit M and 1Dr. Gururaj P. International Journal of Current Research

Vol. 4, Issue, 12, pp.029-031, December, 2012

76. K Mc Callion et al progression in the understanding & treatment of Chronic fissure in ano ,JCDR/2014/10480.4925.

# PROFORMA

**Patient Details**

*Name:* *Age/Sex:* *IP. NO.:*

*Address:* *Occupation:* *Contact No:*

**Complaints**

| *Chief complaints* | *Duration* |
|---|---|
| *Pain* | |
| *Bleeding Per Rectum* | |
| *Constipation* | |
| *Pruritis* | |

**History**

| *Past History* | *Yes/no* | *Personal History* | |
|---|---|---|---|
| *Tuberculosis* | | *Diet* | *High/low fiber* |
| *Inflammatory Bowel Disease* | | *Fluid intake* | *>1.5/<1 l per day* |
| *Previous Perianal surgeries* | | *Alcoholic* | *Yes/no* |
| *Pregnancy* | | *smoker* | *Yes/no* |
| *Cardiovascular Diseases* | | *Bowel habits* | *Regular/ irregular* |

**Examination**

***General***

| *Nourishment* | *Anaemic* | *Icteric* | *Cyanosed* | *Clubbing* | *Pedal edema* | *Pulse* | *B.P* | *Temp* | *Wt* |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |

***Local***

| ***Inspection*** | *Fissure site* | *Number* | *Sentinel Pile* | *Discharge* | *Fistulous opening* |
|---|---|---|---|---|---|
| *Sim's position* | | | | | |

| ***Palpation*** | *Tenderness* | *Anal Tone* | *induration* | *Discharge* |
|---|---|---|---|---|
| | | | | |

| ***Proctoscopy*** | *Anal mucosa* | *Haemorrhoids* | *Internal opening* |
|---|---|---|---|
| | | | |

***Systemic***

| *CVS* | *RS* | *Abdomen* | *CNS* | *Musculoskeletal* |
|---|---|---|---|---|

**DIAGNOSIS**

## Investigations

*Hb:* *RFT:* *RBS:* *CXR:*
*ECG:*

## Management plan

*High fiber diet*
*Plenty of oral fluids*
*Laxatives*
*Sitz bath*

A Chemical Sphincterotomy with 2% Diltiazem Gel T/A thrice daily

B Surgical Internal Sphincterotomy under Spinal

| | |
|---|---|
| for 6 weeks | Anaesthesia |
| •Itching<br>•Headache<br>•Vertigo<br>•Recovery time | •Bleeding<br>•Pain<br>•Infection<br>•Recovery Time |

**Post Intervention Follow up**

| *Timeline* | *Pain score** | *Bleeding PR* | *Healing of the Fissure* | *Incontinence score*** | *Recurrence* |
|---|---|---|---|---|---|
| *2nd week* | | | | | |
| *4th week* | | | | | |
| *6th week* | | | | | |
| *8th week* | | | | | |
| *10th week* | | | | | |

**Pain score:0-3mild/3-7moderate/>7severe*

***Wexner incontinence score: 0-complete continence/1-7Good continence/8-14Moderate continence/15-20severecontinence. Incontinence if + (Temporary/Permanent)*

*Work resume time:* *Recovery time:*

**Final Inference**

| SUCCESS | FAILURE | RECURRENCE | SWITCH OVER A B |
|---|---|---|---|

# INFORMED CONSENT

I, Dr.Balasubramanian, Post graduate student in Department of General Surgery conducting a dissertation work for award of MS degree in General Surgery.

The topic for the study **is "A Prospective Interventional Study between Chemical Sphincterotomy using 2%Topical Diltiazem And Surgical Internal Sphincterotomy in the management of Chronic Fissure in Ano."**

**Objectives:**

1. To assess and compare the efficacy and morbidity of topical application of 2% Diltiazem gel with that of Lateral internal sphincterotomy in patients diagnosed with chronic anal fissure.

I,_____ have been told in a language that I understand (_____) about the study. I have been told that this is for a dissertation procedure, that my participation is voluntary and I he/she reserve the full right to withdraw from the study at my own initiative at any time, without having to give any reason, and that decision to participate or withdraw from the study at any stage will not prejudice my/his/her, rights and welfare. Confidentiality will be maintained and only be shared for academic purposes.

I hereby give consent to participate in the above study. I am also aware that I can withdraw this consent at any later date, if I wish to. This consent form being signed voluntarily indicates agreement to participate in the study, until I decide otherwise. I understand that I will receive a signed and dated copy of this form.

I have signed this consent form, before my participation in this study.

Signature of the subject:

Date:

Place:

Signature of the witness:

Date:

Place:

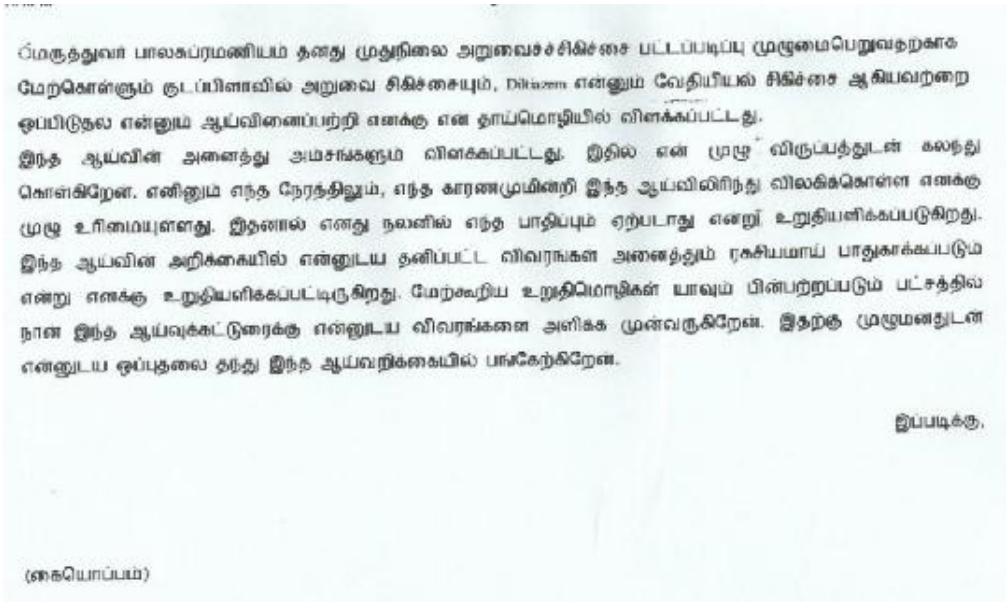
I hereby state that the study procedures were explained in detail and all questions were fully and clearly answered to the above mentioned participant /his/her relative.

Investigators signature:

Date:

Place:

Contacts address:



மருத்துவர் பாலசுப்ரமணியம் தனது முதுநிலை அறுவைச்சிகிச்சை பட்டப்படிப்பு முழுமைபெறுவதற்காக மேற்கொள்ளும் குடற்பிளாவில் அறுவை சிகிச்சையும், Diazem எனும் வேதியியல் சிகிச்சை ஆகியவற்றை ஒப்பிடுதல என்னும் ஆய்வினைப்பற்றி எனக்கு என தாய்மொழியில் விளக்கப்பட்டது.

இந்த ஆய்வின் அனைத்து அம்சங்களும் விளக்கப்பட்டது. இதில் என் முழு விருப்பத்துடன் கலந்து கொள்கிறேன். எனினும் எந்த நேரத்திலும், எந்த காரணமுமின்றி இந்த ஆய்விலிருந்து விலகிக்கொள்ள எனக்கு முழு உரிமையுள்ளது. இதனால் எனது நலனில் எந்த பாதிப்பும் ஏற்படாது எனறு உறுதியளிக்கப்படுகிறது. இந்த ஆய்வின் அறிக்கையில் என்னுடைய தனிப்பட்ட விவரங்கள் அனைத்தும் ரகசியமாய் பாதுகாக்கப்படும் என்று எனக்கு உறுதியளிக்கப்பட்டிருக்கிறது. மேற்கூறிய உறுதிமொழிகள் யாவும் பின்பற்றப்படும் பட்சத்தில் நான இந்த ஆய்வுக்கட்டுரைக்கு எனுடைய விவரங்களை அளிக்க முன்வருகிறேன். இதற்கு முழுமனதுடன் எனுடைய ஒப்புதலை தந்து இந்த ஆய்வறிக்கையில் பங்கேற்கிறேன்.

இப்படிக்கு,

(கையொப்பம்)

## KEY TO MASTER CHART

**FISSURE TYPES**

A-ANTERIOR

P-POSTERIOR

A+P- ANTERIOR &POSTERIOR

**IMMEDIATE POST PROCEDURE COMPLICATIONS**

P- PAIN

I- SURGICAL SITE INFECTION

B-SURGICAL SITE BLEEDING

IT-ITCHING

H-HEADACHE

## BLEEDING PER ANUM

0-NIL

1-OCCASIONAL BLOOD SPOTTING IN STOOLS(MINIMAL)

2- BLOOD STAINED STOOLS(MILD)

3-FRANK BLOOD IN STOOLS(MODERATE)

4-BLOOD CLOTS PASSING PER RECTUM(SEVERE)

## COLOR CODING

| | |
|---|---|
| | GROUP A |
| | GROUP B |
| | GROUP A FAILURES |
| | GROUP B FAILURES |
| | DROPOUTS |
| RED TEXT | RECURRENCE |